Improving medical adherence in atopic eczema treatments:

Designing supportive tools for at-home treatment.

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Improving medical adherence in atopic eczema treatments: Designing supportive tools for at-home treatment.

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Terminology

FTU: Fingertip units

AD: Atopic Dermatitis

QoL: Quality of life

TC: Topical corticosteroids

EASI: Eczema area and severity index

WHO: World Health Organization

SDT: Self-determination theory

Executive Summary

Atopic eczema (AE) is an increasingly prevalent and impactful skin condition that significantly affects the lives of both the patient affected by it and their caregivers. The symptoms of AE, such as persistent itching and discomfort, can have an extensive negative impact on the emotional well-being and overall quality of life of those affected by it, thus making effective management crucial. Several barriers, including child resistance, misconceptions among caregivers, and the time-consuming treatment, contribute to low treatment adherence. To address this challenge and contribute to the enhancement of treatment adherence in (childhood)AE, this project aims to develop supportive tools that enable caregivers to apply treatments in a more efficient, accurate, and enjoyable way.

This project is being conducted in collaboration with Erasmus Medical Center while adhering to the design thinking process. This process involves empathizing with the design problem and target group, as well as (physically) exploring and validating proposed concepts. Throughout these design stages, a range of methodologies was employed, including literature research, field observations, morphological charting, and expert and user interviews. The report details the steps taken in designing two supportive tools aimed at improving the treatment experience and adherence for individuals with atopic eczema (AE).

The initial tool developed in this project is a device aiding a more precise dosing mechanism. It serves as a translation of existing application methodologies. The purpose of this product is to reduce treatment mismatch caused by a lack of understanding of dosing methodologies, thereby addressing non-adherence issues. The dosing mechanism is meant to act as a universal solution, compatible with existing cream and ointment tubes (Figure 1).

Furthermore, the second tool is specifically designed to complement the first tool by providing a visual representation of the appropriate skin surface for each dosed unit. The concept also incorporates various textures to allow for the comparison of healthy skin versus AE-affected skin. By shaping the measurement tool in the form of a stuffed animal, it contributes to heightened relatedness to the child, while also involving them in the treatment process (Figure 2).

Drawing from the comprehensive user and expert research, this report establishes future recommendations for the further development of the concepts. Additionally, a roadmap is provided to bring structure to and help prioritize these recommendations. Both concepts demonstrate promising results, indicating the need for further research and elaboration.

Figure 1: Concept 1

Figure 2: Concept 2

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1 Assignment & Approach

This chapter introduces the project's relevance, initial scope, and approach.
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1.1 Introduction

Atopic eczema (AE), also known as atopic dermatitis, is an increasingly common chronic skin condition that can severely impact the lives of patients and caregivers (Zuberbier et al., 2006). It is a relapsing, inflammatory disorder that is characterized by dry and extremely itchy skin. The severe itchiness and scratching can result in sleeplessness and skin infections. (Lifschitz, 2015) Worldwide, AE affects up to 3% of adults and approximately 15-20% of children (Nutten, 2015).

In addition to the physical discomfort caused by it, AE also causes emotional distress for both the patient and their family members. This results in heightened levels of stress, fatigue, and depression while significantly lowering their quality of life (QoL) (Gochnauer et al., 2017). The impact AE has on Qol and personal well-being can be compared to the effects of serious conditions such as diabetes, cancer, or even a heart attack (Weiß et al., 2020). Moreover, the stigma associated with AE, like other chronic skin conditions, contributes to lowered social interactions (Gochnauer et al., 2017).

While AE symptoms are troublesome and challenging to deal with, they can in principle be managed successfully, allowing patients suffering from AE to lead their life in a near-normal state (Lifschitz, 2015). Topical corticosteroids (TC) are the most commonly prescribed form of treatment to help patients and caregivers manage AE and its corresponding flare-ups. TC can have various formulas ranging from mild to very potent and can have the consistency of a cream or ointment (Berke, 2012). When TC are applied appropriately, they form a safe and effective means of controlling AE symptoms as well as bettering the patient's QoL (Charman & Williams, 2003).

Although there are diverse challenges and barriers in dealing with AE, especially with young patients, the primary reason for treatment failure is the lack of adherence to topical treatments. Other causes of non-adherence include child resistance and carer beliefs (misconceptions) about treatment. (Santer et al., 2013) A systematic review of existing interventions to enhance adherence has shown that the exploration of new methods to enhance adherence can be as valuable as developing new treatments (Bass et al., 2015).

1.2 Assignment & Problem Definition

Information in this chapter has been established by client presentations and further elaboration meetings.

This assignment was first introduced by the dermatology department of Erasmus MC. It was stated that in current AE treatment trajectories, multiple obstacles are encountered, especially concerning at-home treatment adherence. Two important factors herein are, firstly, the ability of the patient and caregivers to correctly estimate the severity of AE and adhere to treatment accordingly. And secondly, the ability to correctly dose their creams and ointments, especially corticosteroids where under-treatment is often apparent.

The assignment originated from challenges encountered by dermatologists at KinderHaven, an outpatient clinic of Erasmus MC. Patients can be referred to the KinderHaven from various departments including general pediatrics, dermatology, or the general practitioner. During the first appointment at the Kinderhaven, the patient will receive a diagnosis and elaborate treatment plan, followed by a second, check-up appointment after six weeks. After that, there will be an appointment every three months, once the patient shows improvement, this is changed to once every six months or at some point once a year. This means that patient and caregivers are often independently carrying out treatment, so proper understanding and adherence is essential for successful treatment outcomes.

It is apparent to dermatologists that in current treatment trajectories, patients often do not properly adhere to their treatment plan. This can be caused by multiple factors but often relates back to health literacy. Which concerns the ability of an individual to properly understand and use medical information to make health-related decisions for themselves or others. The lack of knowledge often results in undertreatment of some sort. It is thus important to of highly needed to provide support for patients suffering from AE as well as their caregivers, in order to help them correctly apply their prescribed treatments. Currently, they are not provided with many supportive tools in this process, which forces them to depend on their limited knowledge. During check-up appointments, dermatologists often encounter patients whose condition is less improved than would be expected from their treatment plan. This, in most cases, shows the plan has not been followed as it was supposed to.

The two main stakeholders within this project are the patient and the dermatologist. However, since a large percentage of patients are young children, their caregivers also form an extremely important stakeholder. Each stakeholder should uniquely be considered to accommodate to their viewpoint and needs. For the patient/caregiver, it is often unclear which medication they should apply, as well as where to apply it and how much. Whereas, for the dermatologist, it is important to be able to confirm how the patient has used their prescribed medication.

This project aims to design supportive tools which allow patients to apply their medications in a more efficient, and accurate way. Such that it improves overall treatment adherence and allows for more successful treatment results. Current ways of treatment and at-home execution of it will be researched to determine patient obstacles and struggles and provide fitting interventions.

1.3 Design Approach

To help bring structure to this project, the design thinking process is used as the guiding approach. Design thinking is a non-linear and comprehensive methodology that allows the designer to break down the design process into distinct steps, from understanding human needs to a hands-on execution through prototyping and validation (Dam, 2023). According to Dam (2023), it is thus especially helpful for tackling complex problems, where it leads to an elaborate problem solution through an iterative process.

The five stages of design thinking, as per d.school, are summarized below (Dam, 2023):

1) Empathize: This stage revolves around conducting user-centered research to help the designer understand the problem and acquire an empathetic understanding of it.

2) Define: Based on the information gathered during the previous stage, the core problem is established while taking the users' perspective into account.

3) Ideate: Once the problem scope is clarified, it is time to generate according solutions while analyzing the problem through multiple perspectives.

4) Prototype: After the ideation of elaborate concepts, it is time to start building physical explorations to allow further analysis and iterations of each solution.

5) Test: From the physical concept explorations, expert evaluations can be carried out, often leading to new product recommendations.

Overall, this methodology is not taken as a strict protocol but is instead used to create a unique process that is specifically altered to the scope of this project while still involving all five design thinking stages. Extensive methods are then again used to achieve the goal within each stage. For example, context observations during the empathizing stage, or Harris profiling for ideation.

2 Literature Review

As part of the empathize stage (Dam, 2023), extensive literature research is carried out to determine the current obstacles and needs of all involved stakeholders. The findings are structured according to topics found relevant from the assignment brief and further client meetings. (Section 1.2) Each topic is summarized in a correspondent section and the chapter is concluded with the main takeaways.

2.1 Atopic Eczema (Incl. Epidemiology)
2.2 Treatment Adherence
2.3 Health Literacy
2.4 Existing Tools & Technologies
2.5 Takeaways

2.1 Atopic Eczema (AE)

It is widely established that AE is a common chronic skin disease that sets a considerable burden on patients' Qol and on health care resources. It is a multifaceted disease with various contributing complexities. Both genetic and environmental factors have been found to contribute to the onset of AE (Nutten, 2015). The disease is becoming increasingly relevant as its worldwide prevalence is increasing, leading to rising societal implications (Lewis-Jones, 2006).

Epidemiology

The prevalence of AE varies across different parts of the world. According to Flohr & Mann (2013), over 20% of children are affected by AE in the majority of developed countries, and it is also becoming increasingly common among children in low-income countries. Although it is most frequent in children, worldwide 1-3% of adults also suffer from AE (Nutten, 2015).

Generally, AE emerges during early childhood. For 60% of patients, it appears in the first year of life, while 85% of patients develop it before they reach the age of five; for approximately 70% of patients, AE spontaneously vanishes as they are leading up to the onset of puberty (Allenova & Darkens, 2023; Cipriani et al., 2014).

Signs and symptoms of atopic eczema

For further elaboration on the disease, information was obtained from huidhuis.nl (Huidhuis, n.d.). This is a reliable source used by doctors from Erasmus MC, which they also recommended to caregivers to improve their understanding of the disease. To be able to understand and recognize AE, it is important to be aware of its various symptoms. Patients with AE typically suffer from dry, itchy skin, with visible redness and lichenification (skin thickening). In addition to these symptoms being visible, the skin often also feels rough and dry to the touch. The redness of skin, also known as ‘erythema,’ also indicates warmth and swelling. The way AE progresses and presents itself can vary depending on the patient's age group and ultimately differs in each individual child (Huidhuis, n.d.).

AE can be divided into distinct phases: acute and chronic. These phases can either occur simultaneously or sequentially. In the acute phase, AE can be characterized by intense swelling, redness, warmth, and even skin bumps and blisters. These symptoms are combined with intense itching, and this phase can last from days to weeks. During the chronic phase of AE, the redness reduces and instead, the skin becomes flaky and thickened. Patients should stay aware of triggering factors such as water or soap (Huidhuis, n.d.).

Assessing the severity of atopic eczema

To be able to properly assess AE treatment effectiveness and understand its burdens, it is crucial to obtain an accurate measurement methodology for AE severity. Healthcare professionals evaluate the extent and severity of AE by examining the skin while considering the affected skin area, as well as by identifying specific characteristics of the lesions. The eczema area and severity index (EASI) was thus created to provide professionals with a standardized assessment method (Tofte et al., 1998).

The EASI consists of distinct steps that can be efficiently and effectively executed by trained professionals. Below, these steps are summarized according to Hanifin et al. (2022) and the instruction guide as per the British Centre of Evidence-Based Dermatology (HOME - Harmonising Outcome Measures for Eczema; Centre of Evidence Based Dermatology (n.d.).

1) Visually determining the area of involved skin, which happens according to four separate body regions and assigned scores (Figure 3).
2) Assessment of the severity of eczema by assigning a score from 0 to 3 to the following characteristics: Erythema (redness), edema/papulation (elevation), excoriation (abrasion), and lichenification (skin thickening) (Figure 4).
3) Region scoring by the use of a multiplier that considers age group and relative contribution to the overall body surface.
4) Calculating the final EASI score according to the four region scores, resulting in a score of 0-72. This score is then supported by a table for interpretation.

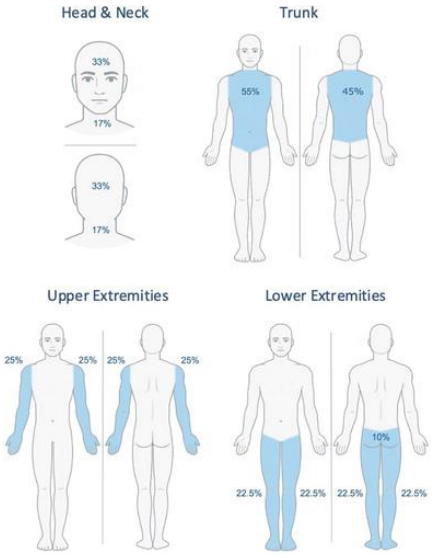

Figure 3: Body regions (Hanifin et al., 2001)

Figure 4: AE Characteristics

(HOME - Harmonising Outcome Measures for Eczema; Centre of Evidence Based Dermatology , n.d.).

Treatment methods

The treatment of AE always involves the use of greasy ointments or creams to hydrate and protect the skin. Additionally, to reduce itchiness and contain symptoms, corticosteroids (hormone ointments) can be prescribed. Depending on AE severity, one of four classes of corticosteroids is advised (Huidhuis, n.d.).

When applying corticosteroids, it is important to properly adhere to the recommended doses to allow for effective results. The fingertip method is thus often recommended to help understand the correct dose. Caregivers or patients can apply fingertip units (FTU) according to specific treatment charts (Huidhuis, n.d.). Furthermore, the general rule can be applied where one FTU of ointment or cream, is applied to a skin surface equal to the surface of two hand palms (Mekkes, 2021).

2.2 Treatment Adherence

Non-adherence to medication has been a well-established problem within healthcare. It has been stated by the World Health Organization (WHO) that among patients with chronic diseases in developed countries, medication adherence is as low as 50% (Lam & Fresco, 2015). Non-adherence is acknowledged as a critical public health concern, due to the negative impact it has on health outcomes, which leads to an increase in healthcare expenses (Lam & Fresco, 2015).

Phases of adherence

A paper by Feldman et al. (2017) proposes that researchers and healthcare professionals take the following phases of adherence into consideration:

1) Initiation: this relates to the earlier phases of treatment, where an agreement is reached on a treatment plan.
2) Implementation: Executing the treatment as agreed upon, while following proper doses and overall treatment guidelines.
3) Persistence: Continuation of proper treatment for a longer period of time.

In current methodologies, there is a lack of consideration of these distinct phases, thus it is recommended to properly consider them in future research to improve the quality of research results or proposed interventions (Feldman et al., 2017).

Barriers in adherence

Diverse research has been carried out to assess treatment adherence within dermatology, and also more specifically within (childhood) AE. A study by Santer et al. (2013) was conducted to identify factors that hinder or facilitate treatment adherence in childhood AE as per the experience of caregivers and parents. Through qualitative interviews, it was concluded that the three main barriers to adherence were: The time-consuming nature of the treatment, child resistance, and carer beliefs. In an attempt to tackle the challenge of child resistance, carers explore different strategies, such as: Involving the child in the treatment process, using gamification or rewards systems, distracting the child, or in some cases applying treatment to a sleeping or physically restrained child (Santer et al., 2013).

The paper by Feldman et al. (2017) also helps in broadening the understanding of the causes of non-adherence to treatments within the dermatology sector. Firstly, the distinction is made between intentional and unintentional non-adherence. Intentional non-adherence is often influenced bybeliefs regarding the necessity of treatment and concern about possible consequences, while unintentional non-adherence can be caused by insufficient understanding or forgetfulness. Ultimately, it is determined that treatment adherence can be enhanced by the creation of a caring and supportive environment and by making patients and carers accountable for their own adherence (Feldman et al., 2017).

Influencing treatment behavior

Patient and carer behaviors can also be assessed according to the self-determination theory (SDT; Deci & Ryan, 1985 ; Deci & Ryan, 2000), which considers the three cognitive needs of autonomy (sense of choice), competence (feeling capable), and relatedness (feeling understood). Within the healthcare domain, the SDT allows for the creation of effective interventions tailored to specific user needs that can positively influence the user's motivation and confidence (Ntoumanis et al., 2020).

2.3 Health Literacy

According to Liu et al. (2020), health literacy (HL) refers to an individual's ability to acquire and understand health-related knowledge, which they can then appropriately utilize to maintain and enhance their health and well-being. An individual with low HL, is more likely to have limited access to healthcare services, which can consequently lead to poorer health outcomes (Berkman et al., 2011).

HL in Dermatology

A paper by Shih et al. (2022) clearly states how patients in dermatology frequently encounter hardships that demand high HL, as active participation in promoting, maintaining, and protecting one's health can remarkably improve outcomes. Furthermore, it is apparent that tools created by researchers to support patients in the ongoing management of their chronic conditions are often better utilized by patients with higher levels of HL. This means that these tools, which are designed to improve health outcomes, could instead widen the gap in care due to the required level of HL (De et al., 2021; Shih et al., 2022). All in all, this shows the demanding need for the creation of suitable, supporting interventions within this context.

HL & Corticophobia

It is a widely accepted understanding that corticophobia, the concerns and fears one has towards the use of corticosteroids, is frequently an issue among carers of (young) patients with AE, which negatively influences treatment adherence (Bos et al., 2018; Mueller et al., 2016). Additionally, Gomes et al. (2022) researched the relationship between corticophobia and the level of HL and found an inverse correlation: Lower levels of HL predicted higher corticophobia.

2.4 Existing Tools & Technologies

Overall, there are not many products on the market that are designed to support patients with AE in their at-home treatment. Bass et al. (2015) conducted a systemic review to explore existing interventions created to improve treatment adherence in childhood AE. Various intervention types were investigated, which all involved the common themes of frequent communication, education, or reminders. Nearly all evaluated interventions showed an increase in adherence; however, considering the limited number of clinical trials, it was established that the focus on developing new strategies to enhance adherence is as valuable as developing new treatments (Bass et al., 2015).

Weiß et al. (2020) introduced the design of a supportive toolbox 'atopi' through a possibility-driven design approach. Atopi is designed to help families with young children who have recently been diagnosed with AE in feeling more supported in their blooming and well-being. The product consists of four different information boxes about the disease, as well as supporting materials regarding patient well-being. While focusing on educating patients and caregivers, it adds a new element to the treatment process to make it more joyous and relatable. Overall, the concept was positively evaluated, showing promising results (Weiß et al., 2020).

To further explore existing tools and gadgets, a benchmark analysis was carried out in the form of market research. Various products were found that are relevant within the scope of this project. An overview of the discovered tools is summarized in Figure 5. This overview includes the 'Atopi Box' by Weiß et al. (2020), as well as other simple dosing mechanisms, such as toothpaste dispensers or sunscreen measuring spoons. Products with a less direct connection to the project, such as the IPL Laser machine or the diaper cream brush, were added in to uniquely help spark inspiration.

Relleve™ delivery system for topical therapy (Palma, n.d.) is another interesting product to highlight. It is the result of a student project focusing on managing psoriasis at home. It aims to solve various problems relating to topic ointment applications by means of a customized ointment pen that automatically dispenses the proper dosage (for details, see https://www.jessepalma.com/work/relleve).

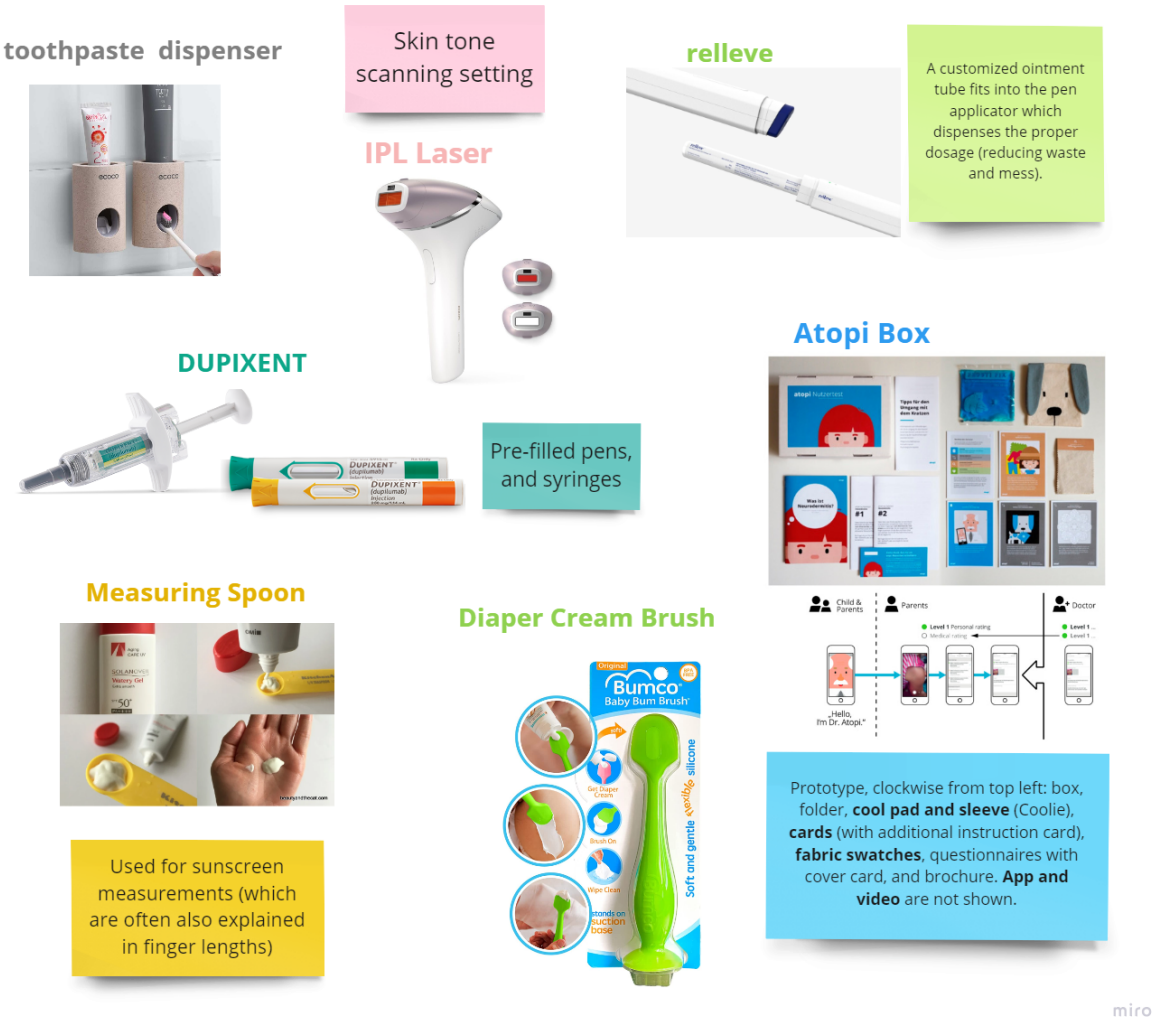

Figure 5: Benchmark existing tools & technologies

2.5 Takeaways

To conclude this extensive literature review chapter, the main takeaways per researched section will be summarized below.

Section 2.1 provides an elaborate description of AE, including its characteristics, and corresponding methodologies. This is an essential section, as it allows for a bettered empathic understanding of the disease and its challenges. Furthermore, the different methodologies will be of high importance for the development of relevant supportive tools for the treatment process and an accurate dosing tool.

Overall, the most relevant takeaways are; Firstly, (young) children are the most affected by the disease, which helps establish a fitting target group. Then, the signs and symptoms are important to consider when designing tools to help better AE understanding among patients and caregivers. Lastly, the methodologies of EASI and FTU provide directly implementable actions that can be translated into supportive tools. E.g. EASI highlights the importance of understanding AE characteristics as well as treating them according to the four body regions. While the FTU provides a great opportunity for a literal translation into a dosing mechanism. The measurement indications, within the FTU application method, leave quite some room for estimation and thus room for error, which can consequently contribute to the problem of under-treatment. Thus, this also re-establishes the need for an effective yet efficient dosing tool.

As for sections 2.2 and 2.3, they add theoretical argumentation for the relevance of this project. As well as provide materials to consider while designing the supportive tools. For example, the phases of adherence can be implemented into the design process, to allow for the creation of a tool that provides the fitting type of motivation. Additionally, the barriers and behaviors corresponding to adherence and HL can be used to formulate design requirements and need statements, which can then be used to form distinct design directions and themes. Examples of corresponding themes are; child resistance, carer beliefs, and misconceptions, or the time-consuming nature of AE treatments.

Lastly, chapter 2.4 mainly helps in starting up the ideation process and sparking up creativity. By seeing what is currently available in the market, the current market gap can be identified, which also reflects which user needs still need to be fulfilled. A more elaborate analysis of these needs will be conducted in chapters three and four while redefining the scope and formulating possible solutions.

In the coming chapters, the information gained through this review will be structured and translated into coherent steps according to the general structure proposed by the design thinking method (Dam, 2023).

3 Scope Defining

The aim of this chapter is to redefine the scope of this project by considering previous findings and adding supplementary information from further steps of the design process. The redefined project scope will be concluded in the form of distinctive design directions.

3.1 Field observations
3.2 Need statements
3.3 Design vision

3.1 Field observations

To further build on and evaluate the abovementioned literature findings, field observations were planned at the KinderHaven, where appointments with patients their caregivers, and doctors were observed. The observations provided input for both check-up appointments and first, intake appointments. This helped identify common struggles and challenges, as well as experience firsthand how the treatment process is first explained to caregivers.

In total, the appointments of four patients were observed. Appointments started off with a recap on the most recent agreed-upon treatment plan while reflecting on the application behavior of caregivers. If the patient is in need of new medications, it will be discussed and adjusted in the plan. The appointment always includes an examination where the doctor will feel and look at the patient's skin and problem areas. Based on the observations, recommendations are given on the required treatment up to the next appointment.

During the observations of these appointments, various challenges in treatment and application were identified. These findings mostly confirmed earlier literature findings, while adding new details to certain themes, by the mention of underlying reasons behind specific challenges or struggles. It was for instance seen how, for one of the patients, undertreatment became apparent due to the lowering of corticosteroid doses while the skin was not ready yet. Which reflects a lack of understanding of severity estimation and appropriate handling. Moreover, for another patient, the carer's misconceptions and distrust in the treatment plan were shown to be caused by experiencing previous treatment plans with lacking results.

More information on the findings and identified themes throughout these observations can be found in Figure 6. The four colors in this figure symbolize the four apparent themes of challenges and struggles. These are comparable with the themes identified within the literature research. Where undertreatment and challenges in the application (incl. distrust in treatment) are part of the research done for section 2.2 (Treatment Adherence). While lack of knowledge is coherent with findings from Chapter 2. 3 (Health Literacy).

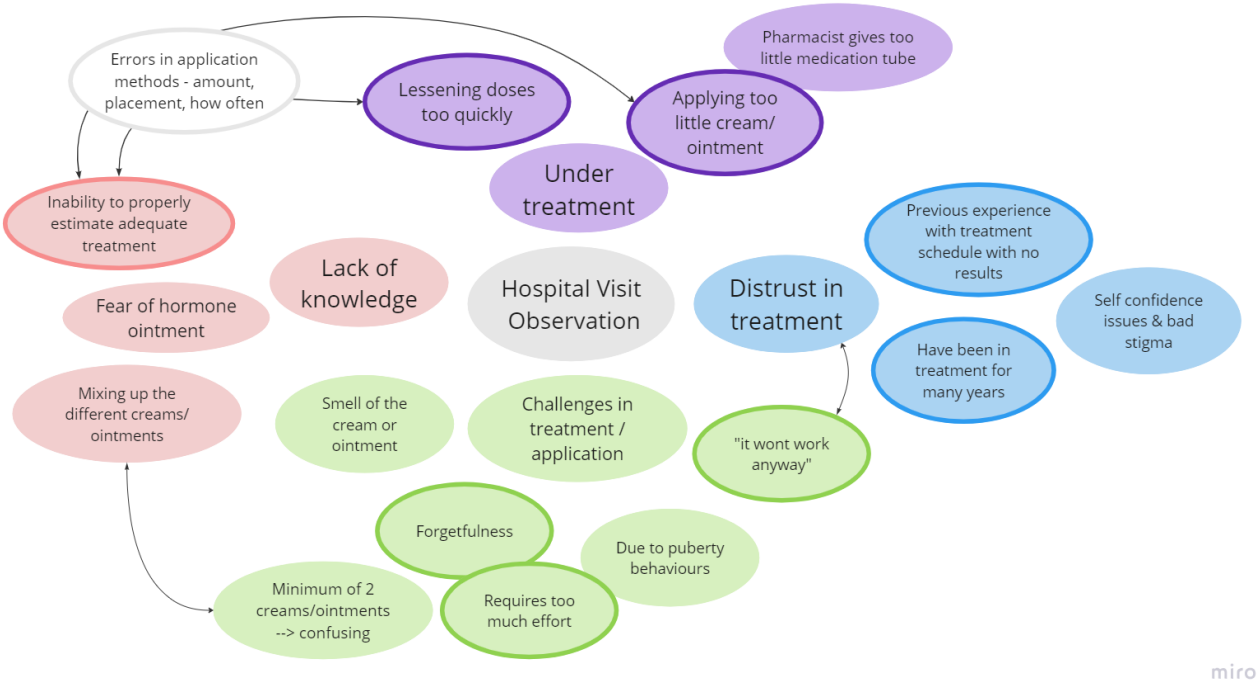

Figure 6: Findings observations of appointment at KinderHaven.

To gain further understanding of the treatment recommendations and methodologies, and reflect on the assignment and problem statement, a doctor at the KinderHaven was consulted. This formed an important step towards re-establishing the problem statement from a more practical perspective, by setting the focus on the design of a dosing tool and other supporting tools.

Building on the literature findings with the observations and additional explanations from the dermatologists, an overview of different treatment options was made (Figure 7). Within the scope of this project, “greasy” and “hormone” (i.e., TCS/ topical corticosteroids) ointments are the main focal point, as they are part of almost all treatment plans. If the scope had to be further narrowed, the focus would be on the application and dosing of TCS ointments. These are more complex to dose and apply correctly, which increases the likelihood of under-treatment, as was explained by dermatologists.

The additional discussion with the doctor was especially valuable to help create an overview of the basic treatment plans and corresponding dosing methodologies. The insights closely matched previous literature findings; the corresponding overview can be found in Figure 7. In this figure, three types of treatment are highlighted: First, the greasy ointments which are part of each treatment plan. Then Hormone ointments (corticosteroids) which are often also part of the treatment as they effectively suppress AE symptoms. And lastly, other therapies that are less frequently prescribed fall outside the scope of this project. The orange color indicates how the information for each treatment can be relevant to this project.

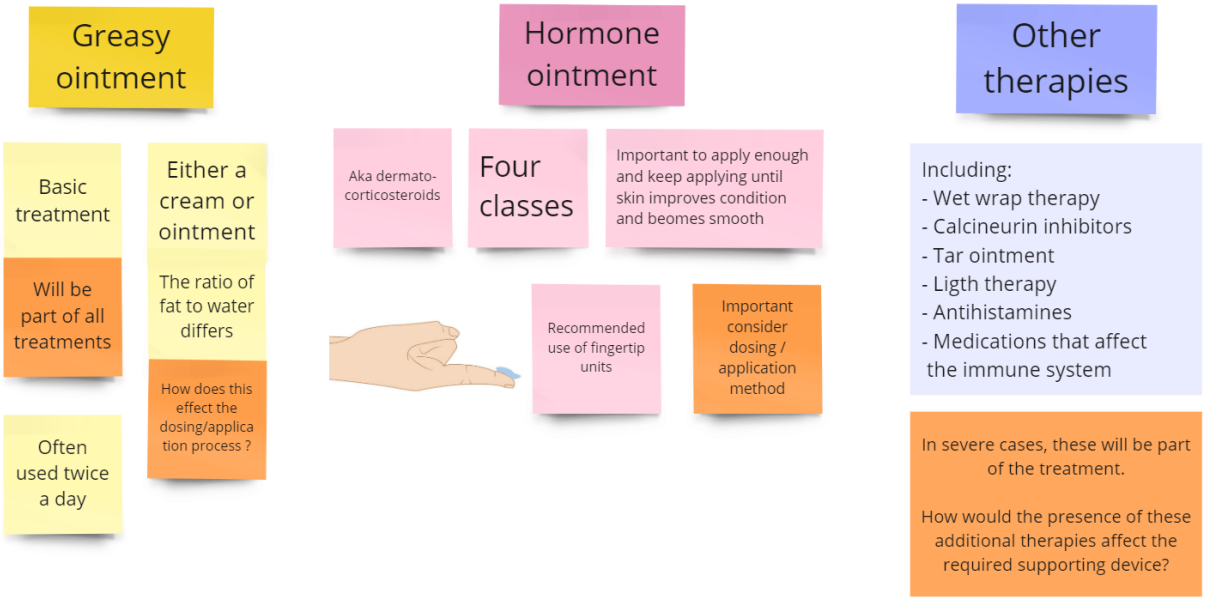

Figure 7: Understanding basic treatment and dosing methodology.

3.2 Need statements

To translate all previous insights into relevant and implementable findings, need statements were constructed. The formation of need statements is an important step within the defining stage of the process, as it allows the designer to align different perspectives prior to the ideation. (Gibbons, 2019) The formation of these statements starts off by noting down a significant observation, which is then rephrased into a problem. From that problem, the actual need statement is formulated, while describing the problem to be solved, for which user population, in which setting, and in order to reach which result. (Figure 8)

These detailed need statements are then used to identify common themes and formulate design directions. (Section 3.3) The most crucial user needs are distinguished by a slightly darker color green. These needs are highlighted on the grounds that they have been detected through multiple sources and strongly contribute to the undertreatment of AE. These need statements are also the ones that are most directly implementable into a design concept.

In total, three needs were highlighted, which can be summarized through the following statement: The need to effectively and correctly treat AE at home, with accurate doses and a proper understanding of AE characteristics.

A way to _____ *(solve problem)*
for _____ *(user population)*
_____ *(in given setting)*
in order to _____ *(result in outcome)* .

Observation	Problem	Need
Atopic eczema can be acute (fluid-filled blister, itching, swelling, redness) or in chornic phase (coarser skin lines, fissres, ticker skin, flaking).	These phases can follow each other or occur simultaneously, for the latter; treatment might differ for each phase, making it confusing for the patient to adhere properly.	A way for the patient to identify eczema types at home to properly adhere to the treatment.
Atopic eczema can not be cannot be cured with treatment. But there are several treatments to reduce the symptoms of eczema.	Since the eczema is not cured, patients are part of a long treatment cycle. This can become exhausting and even cause distrust in the system.	A way to provide an explicit treatment cycle for patients at home, in order to be able to stick to the treatment for a long period of time.
Eczema severity is measured according to erythema, edeme, excoriation and lichenification. On 4 different body regions.	Patient needs to have a basic understanding of these charachteristics to be able to assess their condition.	A way to demonstrate the different characteristics of eczema, for patients at home to properly identify their condition and treat accordinlgy
Finger tip units are used for the application of hormonal ointments for a skin surface of 2 hands.	Patients struggle to define finger tip amount, as well as correctly estimate the according skin surface. This often causes undertreatment.	A way to measure the FTU and according skin surface for patients at home, to prevent undertreamtent
Carer beliefs create a significant barrier to treatment adherence of atopic eczema.	Carers concerns about certain treatments side effects or dangers around the use of topical steroids can result in under-treatment.	A way to establish accordance with the patient carers to properly adhere to treatment at home.
Atopic eczema treatments are very time consuming by nature. (All patients will have a minimum of two creams/ointments, and need to reapply)	The time consuming nature of treatment, results into lower treatment adherence, and accordingly also under-treatment.	A way to effeciantly treat eczema for patients at home to improve adherence and prevent under-treatment.
Intentional non-adherence depends on personal need for treatment and concerns about range of potential consequences.	When patients do not feel the need for treatment or the gravity of potential consequences, they will not adhere to treatment, causing under treatment.	A way to understand the importance of proper treatment for eczema patients and their carers to prevent under-treatment.
Low health literacy is a perdictor for a higher corticophobia.	Due to higher corticophobia, hormonal ointments are not properly applied. Again causing undertreatment.	A way to maintain an understanding of eczema and its treatment for patient and their carers to prevent corticophobia and undertreatment.

Figure 8: Need statements

3.3 Design Directions

The abovementioned need statements can be used to bridge the design process from defining to the ideation phase. This can be achieved by using the most critical statements to generate initial design directions. During this step, relevant insights from the literature review and field observation were also considered.

As a first step towards the formulation of sensible design directions, various themes were gathered to help set up an inclusive ideation. Based on the challenges and struggles within AE treatment processes, the following themes were compiled:

- Undertreatment
- Lack of knowledge
- Child resistance
- Carer beliefs and misconceptions
- Time-consuming treatment
- Lengthy and continuous treatment cycle

From these themes, different research questions were formulated to help aid the formulation of the design directions.

1. How can the design of supportive tools prevent undertreatment in AE?
2. How can supportive tools in the AE treatment help the patient in updating their dermatologist on the amount of medication used?
3. How can the overall treatment experience be redesigned to lessen child resistance and allow for a more enjoyable interaction?
4. How can the treatment experience be redesigned to either become or feel less time-consuming?

From these research questions, various factors regarding the design become apparent. Firstly, the design must include some sort of dosing tool. While also redesigning the overall experience to feel more pleasant and efficient.

The initial design direction can thus be formulated as: Designing supportive tools that allow for a more effective, efficient yet pleasant treatment experience for the caregiver, patient, and dermatologist.

4 Ideation

This chapter highlights the ideation process, showcasing the numerous solutions and corresponding assessments according to exhaustive criteria.

4.1 Design Vision

The initial design direction (section 3.3), can be used as a building block to help formulate a more inclusive and thorough design vision that acknowledges the assignment and problem statement to its full extent.

To spark creativity and allow for the creation of a unique design vision, the Kees Dorst method is applied (Dorst, 2015). This method is proposed as part of the design thinking model and revolves around conducting a theme analysis which results in a comprehensive analysis of the fundamental factors which drive the target user's needs, motivations, and experiences. (Mattson, 2021; Dorst, 2015)

As a first step within this method, user challenges and struggles are used to formulate relevant cause statements, which are then re-iterated to formulate comprehensive design directions. These 'cause statements' build on previous findings while adding in assumptions to further explore the topic. Two instances are elaborated below:

Kees Dorst Method 1.1

Because of the time-consuming nature of AE treatment, children feel upset and bored, leading to child resistance.

Due to child resistance, parents apply medication quickly and insufficiently, causing undertreatment.

As undertreatment prevents corticosteroids from optimal working, the eczema treatment process needs to be redesigned into a more time-effective, enjoyable form.

This set of statements leads to the formulation of the following design direction: Providing dosing and application tools that allow for a more efficient process, while adding playful elements that help make the process feel more enjoyable and less time-consuming.

miro

Kees Dorst Method 1.2

Because caregivers face corticophobia, they apply lower doses of corticosteroids than required to the child's skin.

Due to the application of lower corticosteroid doses, patients and caregivers are not properly adhering to the treatment as prescribed and are under-treating AE.

Due to the undertreatment, corticosteroids are not functioning to their full extent, thus it is important to highlight the need for proper treatment adherence and decrease the room for own estimation and errors.

Correspondingly, the following design direction is formulated: Providing a dosing tool can help prevent undertreatment by providing a strict and measurable application process while reducing the room for caregivers or patients to (subconsciously) make incorrect estimations whilst being affected by corticophobia.

miro

Kees Dorst Method 2.1

To help spark further inspiration for the formulation of a unique and comprehensive design vision. Various statements were defined which approached AE treatment as if it was another everyday (enjoyable) task. This led to unique comparisons and formed new key experiences to be included in the vision.

Statements:

If AE treatment is approached as if it is a game, it should be fun, exciting, involve friends, and make you competitive.

If AE treatment is approached as if it is having a meal, it should be carefully prepared, then thoroughly enjoyed (together), and lastly cleaned up.

If eczema treatment is approached as if it is a car ride, it should have a clear end goal or destination and be enjoyed by listening to the radio or chatting with other passengers.

If eczema treatment is approached as if it is a bedtime story, it should feel safe, like a bonding moment, and bring the child to ease.

miro

Vision Formulation

While taking both the design directions and the established key experiences into consideration, the design vision was formed as follows; Designing supportive tools that allow caregivers of children with AE to apply their treatments in a more efficient, accurate, and enjoyable way; such that it stimulates the bonding experience between the carer and child, making the overall process feel more pleasant and relatable, like other daily tasks.

Along with the formation of the vision, various decisions were made that influenced the design scope. Namely, focusing on children with AE and their caregivers as the main stakeholder. As children are the predominant patients suffering from AE (Allenova & Darkens, 2023; Cipriani et al., 2014). Additionally, it was decided to focus on designing tools that influence the overall experience, instead of focusing on a specific problem. The expected end result is thus to deliver multiple supportive tools which can be simultaneously used.

4.2 Solution Brainstorm

After the extensive explorations and re-scoping execute to formulate relevant design directions and the inclusive vision, it was time to start ideating and structuring all different problem solutions.

The morphological graph was chosen as the methodology to explore different solutions and concepts and rank them accordingly. This method was chosen since it helps bring structure to the different concepts by dividing them into sub-functions (Van Boeijen et al., 2013). New concepts were also formed while focusing on the sub-functions and how they could contribute to the main function and form one coherent set of tools.

Morphological chart

Prior to visualizing the morphological chart according to its subsections, a clear overview of all different solutions was created (Figure 9). Within this overview, each concept is shortly described by a title, what it does, why it is useful, and where possible is supported by a representing image. The figure shows three different outline colors for the concept blocks, where purple is a concept that can be translated into a physical tool, blue is a concept direction that can be given in the form of a recommendation or general advice to the client and medical professionals, and lastly, the pink block represents an element that can be implemented into other concepts.

The overview contains concepts such as possible dosing tools, solutions for bettering the caregiver's understanding of AE and corresponding treatment methodologies, behavior-tracking products, and more generalized suggested mentalities.

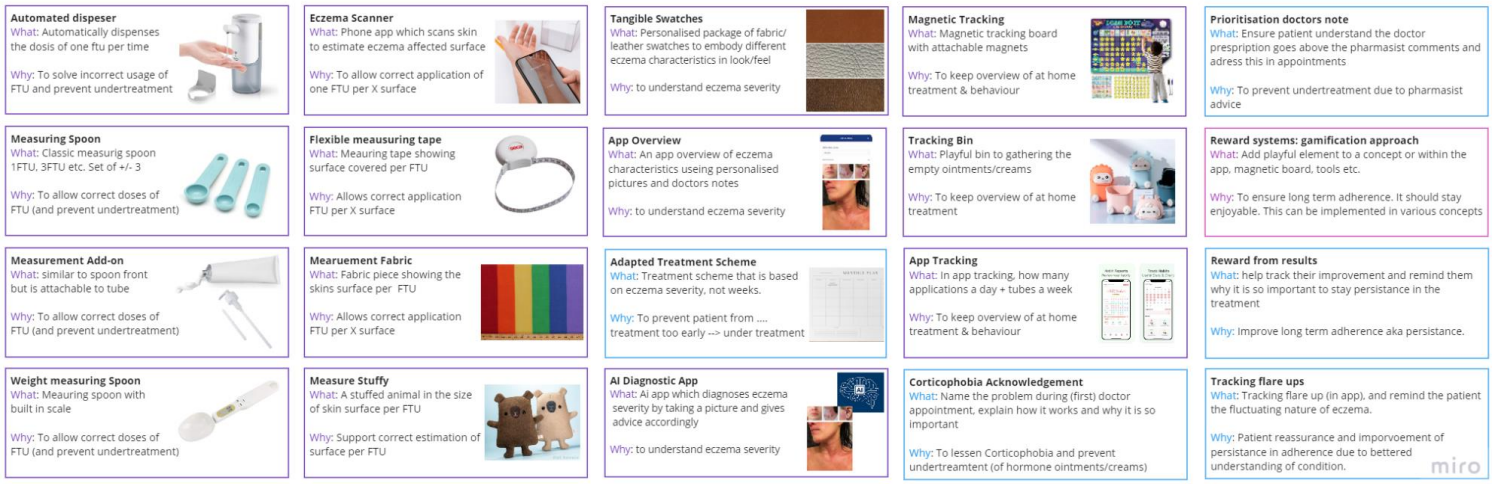

Figure 9: Overview of all sub-solutions/concepts

The morphological chart can now be plotted, inserting all solutions from Figure 9. The chart starts off by naming the main function of the required design tools. Then, the solutions are divided according to the different sub-functions (Figure 10).

The defined sub-functions are also coherent with part of the previously determined research questions (Section 3.3). Where the first, and main research question: “How can the design of supportive tools prevent undertreatment in AE?”, connects to the creation of a dosing and measuring tool. As well as the more global eczema understanding. While the second research question: "How can supportive tools in the AE treatment help the patient in updating their dermatologist on the amount of medication used?", is reflected by the fourth sub-function of proposing tracking systems. The remaining research questions are reflected within the specific solutions and the list of requirements used to evaluate them.

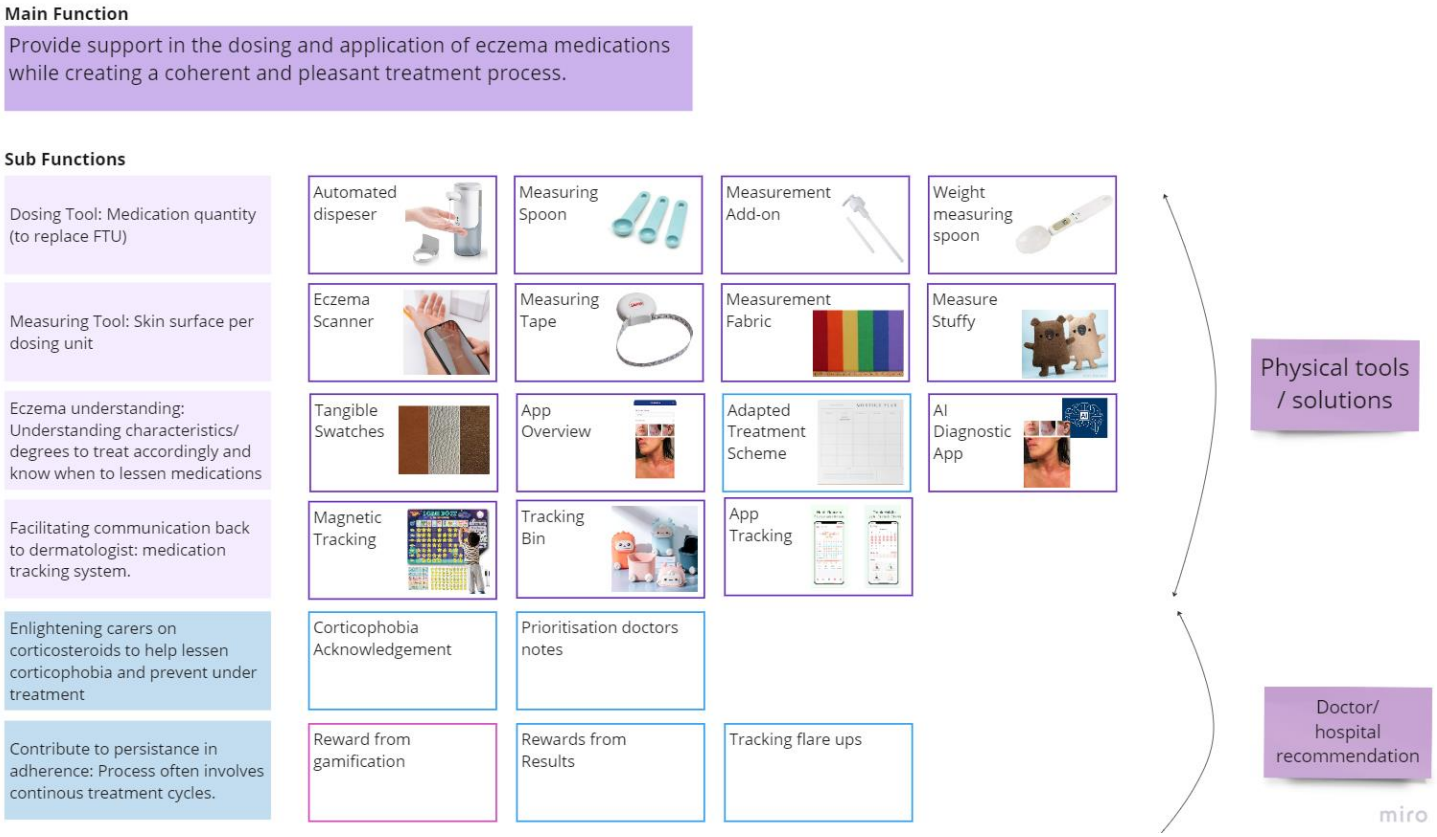

Figure 10: Morphological chart

The morphological chart can then be used to decide upon the tools to be developed, by selecting the best solution per sub-function. In order to objectively rank these solutions and concepts, a requirement list is necessary, which will be specified in the next section (4.3).

4.3 Design Requirements

Within this section, the list of design requirements is set up according to diverse literature findings, observations, and the priorly defined design vision and direction. Each requirement is supported by argumentation on applicability to the project scope.

Requirement List

Child Friendliness: As literature has shown, a big barrier to treatment adherence in childhood eczema is child resistance (Santer et al., 2013). Thus, it is of high importance that the supportive tool is designed with the child in mind, consisting of features that are likable to them.

Ease of use: The product or service should be designed such that it can be understood and easily used by each patient or caregiver. The establishment of complex tools can result in the problem of widening the gaps in care instead of improving outcomes due to the requirement of certain abilities or skills (Shih et al., 2022). The risk of this problem can be reduced by improving the overall ease of use and understandability of the tool.

Time efficiency: The time-consuming nature of eczema treatment forms another barrier to treatment adherence in (childhood) AE (Santer et al., 2013). It is thus important that the

supportive tools do not significantly increase this time burden by adding unnecessary, tedious, or lengthy steps. This can be a difficult barrier to tackle, as current treatment processes are already time efficient by solely consisting of required steps. However, it does provide a factor according to which different concepts can be weighted. Instead of solely focusing on the time spent, a good alternative requirement is to improve the experience during this time, which makes the overall experience *feel* less time-consuming. Which gives the alternative requirement of **Enjoyability. ****As these are alternative requirements, the tool should score well on either of them.*

Stimulates bonding: The design vision revolves around redesigning the treatment experience to stimulate child-parent bonding and in that way improve the overall experience. This requirement can be accessed by the opportunities a concept provides for the parent and child to interact in a playful/enjoyable way. **This requirement might not be as relevant for every sub-function, but it is important that at least one product can contribute to this function to be able to achieve the design vision.*

Fulfillment of human needs: The vision builds beyond improving adherence, the tools should improve the experience and make it enjoyable for both parent and child and create a safe environment where they can bond. To achieve this, it is important to integrate the fulfillment of human needs like **autonomy**, competence, and **relatedness** (Deci & Ryan, 2000; Ntoumanis et al., 2020) It is especially important for the parent to feel like they have autonomy within the treatment by feeling like they have a say. While relatedness involves the child, their feeling towards eczema, the surrounding stigma, and how they can connect with others within this matter.

Functional Efficiency: How well the solution actually solves the problem. This requirement also relates back to the basic human need for competence. It should not only be considering the functional efficiency from a problem-solving perspective but also the experience of effectiveness by the carer.

Cost efficiency: Within the healthcare context, it is often a challenge to provide solutions that are effective yet cost-efficient. Cost efficiency is especially important in this context due to the economic and financial burden of AE already being significant (Adamson, 2017).

Accuracy: Relates back to functional efficiency, but is especially relevant for the design of the dosing tool and estimation of the skin surface. These tools must provide accurate results to provide effective solutions and help lessen under-treatment.

Cleanability: The tool should be easy to clean and disinfect, as it should not induce any hygienic risks to the patient.

4.4 Solution Assessment

The solutions and concepts can now be assessed according to the morphological chart's division and the defined list of requirements. To allow for a structured evaluation approach, the Harris Profile method is used. This method was chosen since it gives a visual display of the evaluation and leaves room for the designer to build upon their intuition (Van Boeijen et al., 2013).

Harris Profile

For each sub-function, the requirements are arranged according to significance, where the most important is at the top of the chart and the least important is at the bottom. This is an intentional decision, as it will help with the visual assessment of each solution. Moreover, the order of importance of requirements can also differ from one sub-function to another. For example, child-friendliness is moved down the chart for the sub-function of dosing tools, as it will mainly be used by the caregiver, especially in early childhood years.

Figure 11 shows the Harris profiles for the dosing tool concepts, where the measurement add-on clearly ranks highest, and is thus the concept that will be further developed in the next steps of the design process.

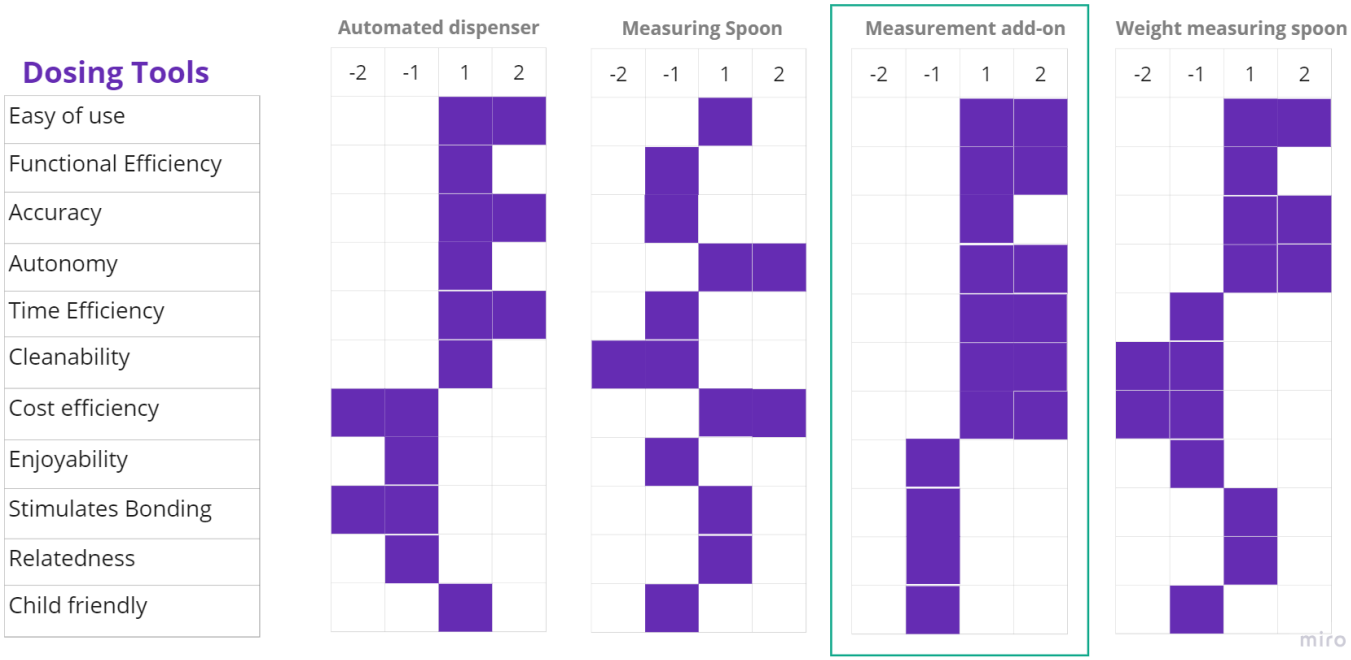

Figure 11: Harris Profiles - Dosing Tools

Then, for the evaluation of the surface measurement concepts, the Harris profiles show the best ranking for the 'Measure Stuffy' concept (Figure 11). It scores especially well on the requirements relating to improving the overall experience and child-caregiver interactions.

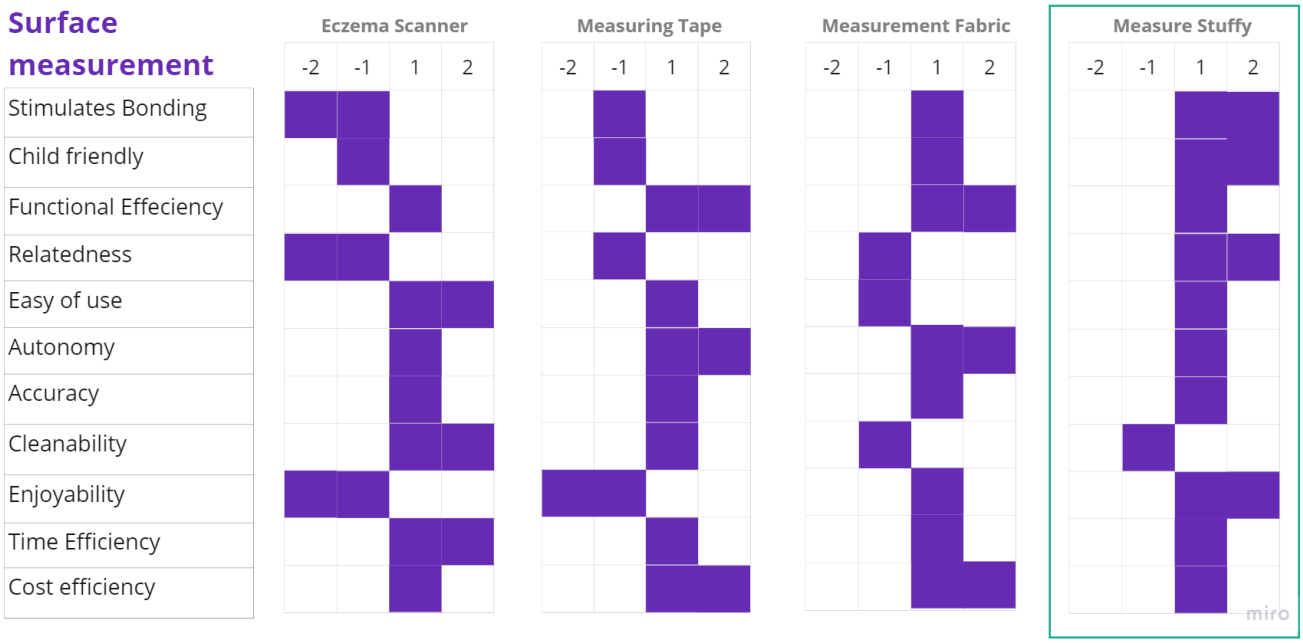

Figure 11: Harris Profiles - Surface Measurements

Next, for the concepts on elaborating AE understanding, the Harris profiles again show a clear leading concept, namely the use of tangible swatches (Figure 12). This concept strongly jumps out from the other concepts, as it provides great opportunities for improving relatedness while stimulating bonding in a child-friendly way. Moreover, this concept can be integrated into the 'Measure Stuffy' concept from the surface measurement function, creating an inclusive, sensible product.

Figure 12: Harris Profiles - Eczema Understanding

Lastly, the Harris profiles for the tracking system showed the best ranking for the tracking bin concept. However, compared to the previous profiles, this sub-function had the closest runner-up, which was the magnetic board. Both these concepts still have a lot of room for exploration. But ultimately, the tracking bin is still preferable due to superior scores on functional and time efficiency, and accuracy (Figure 13).

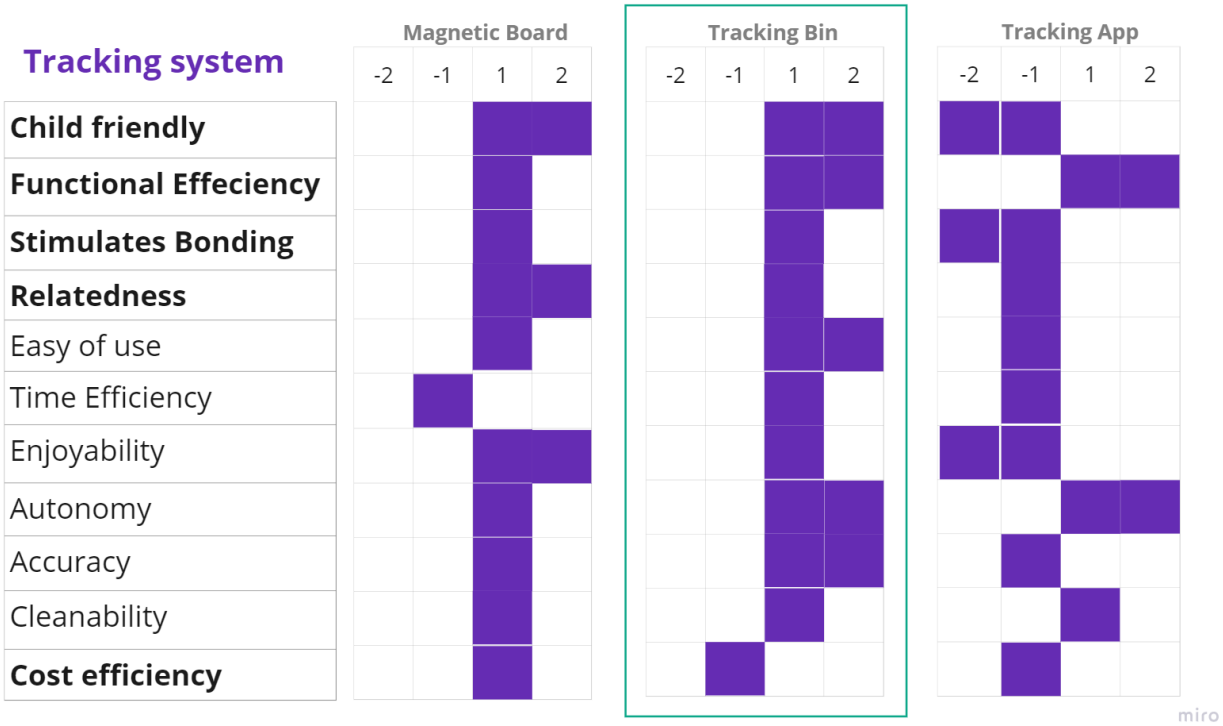

Figure 13: Harris Profiles - Tracking system

All in all, the ideation and evaluation process led to the decision upon the following three design concepts:

1) Add-on dosing mechanism
2) Measure Stuffy (incl tangible swatches)
3) Tracking bin.

These concepts will be further explored and elaborated in the next section.

5 Conceptualization

Within this chapter, the three above-described concepts will be elaborated into more exhaustive concepts. For each concept, various steps will be highlighted depending on their relevance and contribution to the design vision. All concepts will first be further explored through existing tools and inspiration points.

5.1 Dosing Mechanism

Early in the design process, the problem statement and design direction involved the need for a dosing tool that helped the patient or caregiver apply sufficient corticosteroids. Through the ideation and evaluation process, the specified design direction of a dosing *add-on* mechanism was determined.

As a first step to the further development of this concept, inspiration was sought from existing tools and mechanisms. A corresponding overview was then made for these tools while exploring different design possibilities and identifying relevant challenges (Figure 14).

Figure 14: exploration dosing mechanism

As Figure 14 shows, multiple types of mechanisms were explored; Firstly, various shapes of the classical pump mechanism, as well as the working behind the mechanism as seen in the illustration on the bottom left (Jc, 2020). Then, more unique designs such as a rotating dosing bottle (UnoDose, 2020) or the mechanism that is often used for serums. Lastly, an example of a (sunscreen) measuring spoons (Renee, 2017) was also added into the overview, along with an implemented version which goes directly on the tube. Ultimately, this board of inspiration helped formulate various points of consideration to take into the next steps of conceptualization.

While exploring different mechanisms, the realization was made that a complex pump mechanism is not a logical direction within this context. Since the corticosteroid tubes are squeezable, and thus, the need for a mechanism to 'pump out' the ointment or cream disappears. Additionally, such a pump mechanism will also unnecessarily take away space from within the tube and would somehow need to accommodate for this. Instead, it makes more sense to squeeze the tube itself, into a mechanism which is integrated in the lid area.

From here, a new brainstorm was carried out to conceptualize possible mechanisms that are solely integrated in the lid area of the tube. As the tube can be squeezed to push out ointment or cream, the mechanisms would need to contain a space that accurately measures the extracted ointment or cream in fingertip units. From this so-called storage and measurement area, the correct doses would then somehow need to be pushed on to the skin. To create a first version of such a concept, inspiration was taken from a syringe, due to its accurate and easy working. The translation from relevant elements of a syringe towards the elements of an add-on dosing mechanism can be seen in Figure 15.

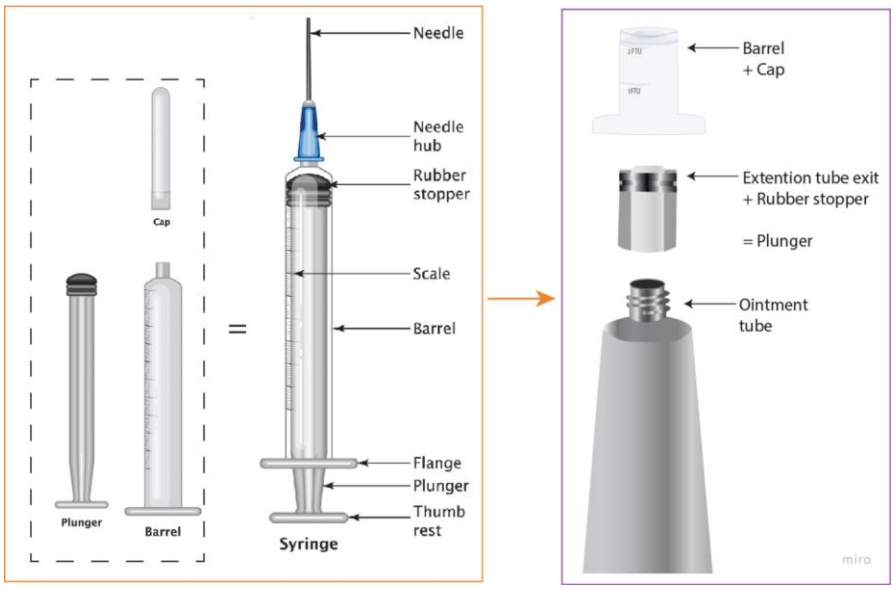

Figure 15: Syringe anatomy (Anna, 2021) to concept anatomy

To further define the syringe inspired concept, a step-by-step illustration was created to show the exact working. (Figure 16). The figure shows 8 steps, which can be explained as follows:

1) Remove the existing lid off the tube.
2) Turn the plunger mechanism onto the tube.
3) Push the barrel onto the plunger to secure in place.
4) Push the container down according to the required doses (1 FTU in this example).
5) Open the cap on the 'barrel' and squeeze the tube to release ointment into it.
6) When the barrel is filled to the desired dose, push it down to extract the cream or ointment.
7) As the ointment comes out, apply it onto the skin that needs treatment.
8) After emptying the barrel by pushing it down, close the lid and leave it until the next treatment.

X) The dosing mechanism can stay on the tube until it's empty, after that it can reused by being placed on a new tube.

Figure 16: Dosing mechanism - Option 1, step by step working explanation.

This concept will need to be further explored through prototyping, as well as evaluated by medical experts. However, various challenges can already be identified, namely:

- The plunger's exit will require a one-way valve, to prevent the ointment or cream from being pushed back into the tube as the barrel is pushed down.
- The barrel needs to be placed securely on to the plunger while still allowing for smooth and easy movement. The required resistance thus needs to be secure yet not significantly hinder the ease of use.
- Pushing down the barrel should not lead to exertion of unnecessary force onto the tube. As this would push out more cream or ointment into the barrel and affect the doses.
- Ergonomic factors should be considered, to ensure the mechanism is comfortable and easy to use by people with a wide range of hand sizes. The mechanism's functionality should not be affected by the user's hand size.
- Lastly, the lid needs to be designed in a more coherent, and connecting manner, to prevent it from getting in the way and allow it to properly close of air passage when closed.

The abovementioned challenges were also influenced by the development of the mechanisms mock-up prototype. (Section 6.1) Another possible pain point from this concept is the need to push the barrel back up after every use. This could result in a more tedious treatment process. Therefore, a second option of the concept was explored, which removed this step by combining both elements (the barrel and plunger) into one, flexible mechanism (Figure 17).

Figure 17: Dosing mechanism - Option 2

The second option of the concept is very similar in working to the first. The main difference is that the storage room, or barrel itself, can be squeezed to push out the cream or ointment. The mechanism consists of one element, which is vertically squeezable and can be closed off with a lid. This mechanism is once again explained in the form of a step-by-step illustration, which can be explained as follows:

1) Remove the existing lid from the tube.
2) Turn the mechanism onto the tube.
3) As the mechanism is secured, open the cap and squeeze the tube to release the ointment into the empty chamber.
4) When the chamber is filled to the desired dose, vertically squeeze it to push out the ointment.
5) As the ointment comes out, direct it towards the skin that needs treatment.
6) After emptying the mechanism and releasing it, it will pop back up with some residue left and the lid can be closed off until the next treatment.

The second option, for the dosing mechanism, again brings its own challenges. Overall, it is expected to be less accurate and have wider dose margins. The dose can be affected by how the mechanism is squeezed, how well it is filled etc. It might also be more fragile.

Four expert interviews were carried out to compare both concept options. Two of the interviews were carried out with a pharmacist, and the other two were with doctors at the dermatology department of Erasmus MC. In short, these interviews led to the selection of the first option of the concept, due to its superiority in accuracy and overall functionality. More details on the insights from these interviews can be found in section 7.1, and the comprehensive interview transcripts can be found in Appendix B.

Furthermore, the insights from these expert interviews and the creation of the mock-up prototype also resulted in a second iteration of the selected concept. The main three adjustments are:

- The addition of a gripping element, visible in blue in Figure 18, to improve the comfort of use. While also preventing the exertion of force onto the tube, when pushing down the barrel element.
- Providing two sizes of the dosing mechanism, one with two FTUs and another one with five FTUs. These can be used as required, according to the degree of AE or the patient's age group.
- Providing a cleaning set, to facilitate the cleaning process of the mechanism when changing from one tube to another one. The cleaning set will consist of various types of cleaning and drying brushes and can be used with water and dish soap. Various tube brushes already exist, as can be seen in Figure 19.

Figure 18: Adjustments in dosing mechanism

Figure 19: Tube cleaning kit (Amazon.nl)

With the consideration of these adjustments, the conceptualization of the dosing add-on mechanism is finalized. In the next chapter, the mechanism will be further developed while working towards the development of a first prototype.

5. 2 Measure Stuffy

In addition to the dosing mechanism, a second tool is required to enable the patient or caregiver to properly adhere to current dosing methodologies. While the dosing mechanism tackles the first part of the problem; understanding and applying according to FTU. A second tool is needed to help explain the corresponding skin surface to which one FTU should be applied. Without this addition, undertreatment can still take place, when one FTU is applied on a too-large skin surface.

From the Harris profile evaluation, the best solution for this sub-function was found to be the 'Measure Stuffy': A stuffed animal, with a body size equal to the skin surface to which one FTU (as per the dosing mechanism) should be applied. In addition to the sub-function of acting as a measurement tool, the Measure Stuffy also reflects the selected solution for improving overall AE understanding. By implementing tangible, textured AE swatches.

The initial visual exploration for the Measure Stuffy can be found below in Figure 20. This figure consists of pictures of existing stuffed animals, which can be used to inspire the form-giving and elaboration of the Measure Stuffy.

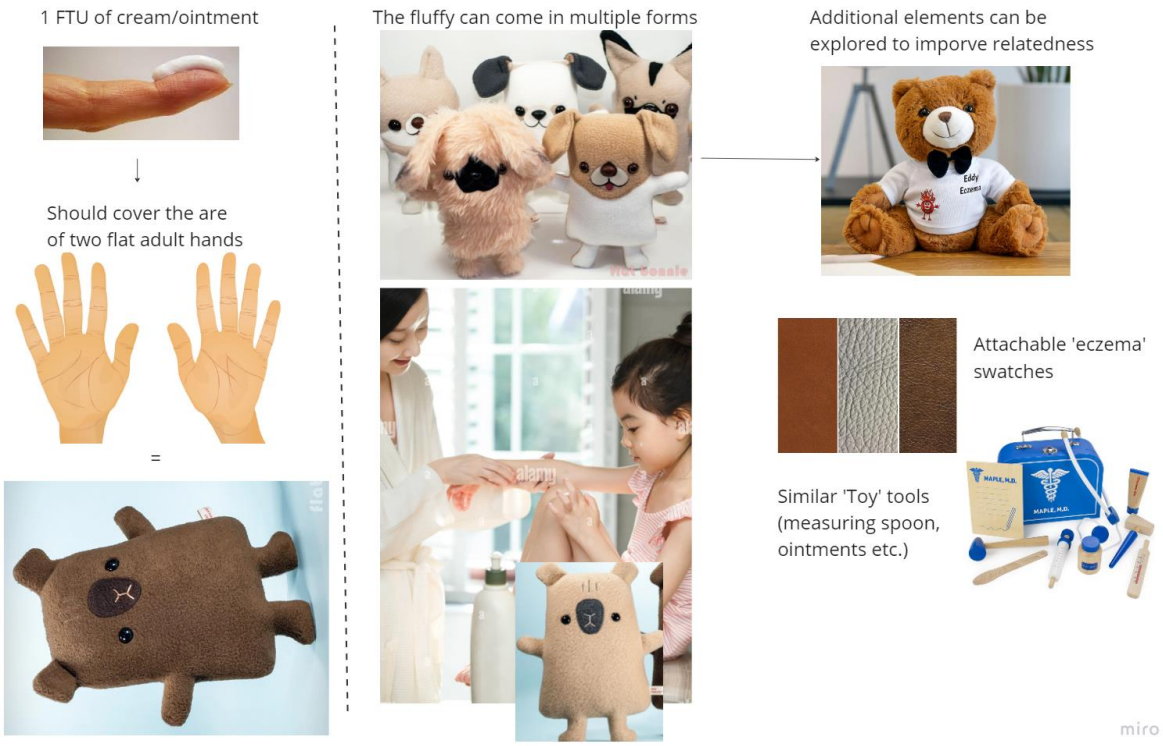

Figure 20: Exploration Measure Stuffy (From existing products)

Although the concept of tangible AE swatches was also included in the exploration of the Measure Stuffy (Figure 20). A separate exploration was executed to further analyze the opportunities within this concept. Within this visual exploration, the AE characteristics (HOME - Harmonising Outcome Measures for Eczema; Centre of Evidence Based Dermatology, n.d.) were considered, as well as different possible leather textures (Figure 21). In addition, these textures aim to help improve overall AE understanding. This concept also aspires to improve child-relatedness by normalizing textured skin and representing it in a teddy bear.

Figure 21: Exploration of tangible AE swatches

Fortunately, the takeaways from both concepts could easily be combined into one. Making the Measure Stuffy a multipurpose stuffed animal helps the caregiver estimate the correct skin surface used for each FTU of ointment. As well as giving them a better understanding of AE characteristics by allowing them to touch different structures. The animal's body can be used to symbolize healthy skin in look and feel. While each extruding body part can be used to communicate various degrees of eczema, by texture and potentially also colors. The Measure Stuffy can then be envisioned as follows:

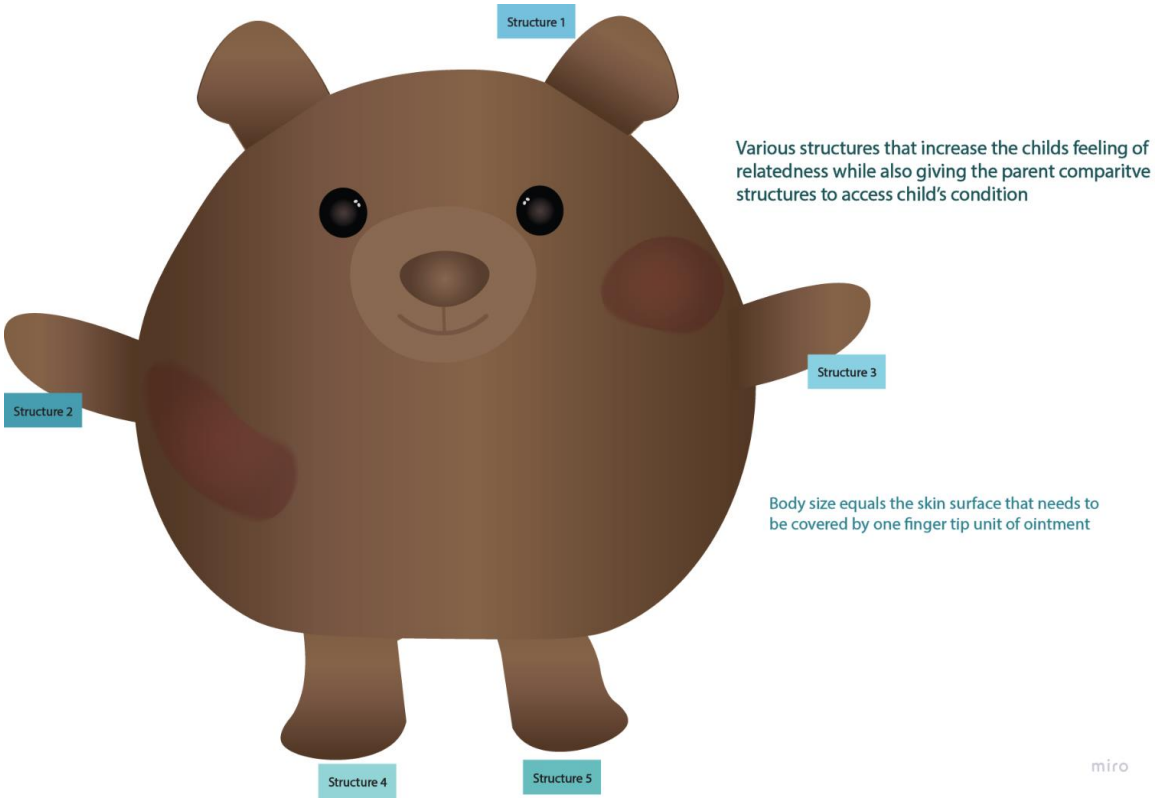

Figure 22: Measure Stuffy - Visual elaboration

Depending on the number of structures to be implemented, the stuffy can take various shapes with more protruding body parts. For example, an elephant also has a large trunk and tail, which provides the opportunity to add more structures to the product (Figure 23). The shape taken by the Measure Stuffy is also influenced by the inclusion or exclusion of skin tones and redness. If this is chosen to not be reflected in the product, an elephant could be a fitting form, as its gray color does not relate to any human skin tones and thus does not exclude patients of certain skin color.

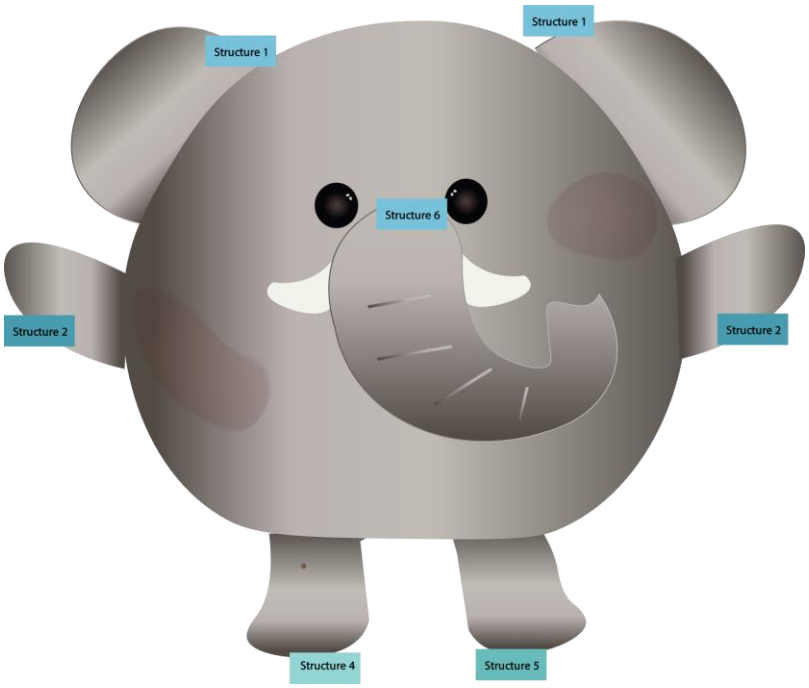

Figure 23: Different iteration of the Measure Stuffy

5.3 Tracking Bin

The last sub-function, which was explored within the ideation stage of this project, was the facilitation of communication and behavior tracking. The highest-ranking tracking tool, according to the Harris profile evaluation, was established to be a playful tracking bin.

Compared to the other two sub-functions, this concept solves a more secondary, less directly measurable problem. Thus, for the further steps of the design process, the focus is instead set on the dosing mechanism and the Measure Stuffy.

However, an initial exploration of the tracking bin is still visualized in Figure 24. Further comments and elaborations on the relevance and form of this concept will be considered as part of the future recommendations in chapter eight.

Figure 24: Exploration tracking bin

6 Prototype Explorations

This chapter highlights the physical explorations that have contributed towards the creation of the first versions of the prototypes for both the dosing mechanism and the Measure Stuffy. The steps are divided as follows:

Dosing Mechanism

6.1 Mock-up prototype
6.2 Sizing experiments
6.3 3D model
6.4 3D print & evaluation

Measure Stuffy

6.5 Material Exploration
6.6 Mock-up Prototype
6.7 Textured Prototype

Dosing mechanism

6.1 Mock-up prototype

To further explore the syringe inspired dosing mechanism and be able to properly convey its working, a mock-up prototype was created. (Figure 25) This prototype has no functional purpose but is solely meant to clarify how the mechanism could look and feel. It was created by altering a 5 ml syringe and an empty 30 ml cream tube.

Figure 25: Dosing mechanism - Option 1, mock-up prototype

This prototype contributed to the definition and confirmation of the mechanism challenges as defined in section 5.1. It also helped in establishing the suspected pain point of needing to push the top barrel back up after each use, which could be quite a hassle. This issue could be solved by providing an enlarged mechanism that fits up to 5 FTU, thus lessening the need to move the mechanism back and forth. All in all, the mock-up prototype highly contributed to the further adjustments of the concept. Mainly referring to the suggested mechanism sizes and the addition of the gripping element.

6.2 Sizing experiments

To be able to translate the concept into a prototype, it is required to determine various factors for the mechanisms sizing. Therefore, two experiments were executed that helped in deciding upon the width of the storage tube (barrel) according to different consistencies and translating FTU into an accurate volume unit. Both experiments will be elaborated below, for further details and pictures of the experiment steps, see Appendix D. The approach for both experiments was also verified by various experts in the dermatology sector during an interactive presentation (for further details, see section 7.1).

6.2a Tube width and corticosteroid consistency - Experiment 1

Aim: To explore the ease of filling up different tube sizes with various corticosteroid consistencies.

Expectations: Especially for thicker consistencies, it will be easier to fill up the narrower tubes that are closer in width to the tubes exit. As it is expected that the thick consistency will push up in original width, making it more difficult to fill up additional volume horizontally and leaving significant air bubbles.

Method: For this experiment, three different tube sizes are cut up to match in volume. These three sizes are then filled up with three different corticosteroids. Where the ease of filling is evaluated according to:

1) The required force to push out the corticosteroid into the tube.
2) How seamless and accurate the tube is at halfway and at fully filled point.

Both conditions were ranked from one to seven, where one was extremely difficult and seven was extremely easy. A ranking of seven was chosen due to its clear neutral point and room for more diverse analysis as compared to a score of five.

Materials

- Tacrolimus monohydrate ointment - 30mg (Thinnest consistency)
- Mometasone ointment - 30 mg (Medium consistency)
- Clobetasol (propionate) cream - 30 mg (Thickest consistency)
- 2 ML tube → cut up to a volume of 2 ML
- 5 ML tube → cut up to a volume of 2 ML
- 10 ML tube → cut up to a volume of 2 ML

Figure 26: Corticosteroids & consistencies

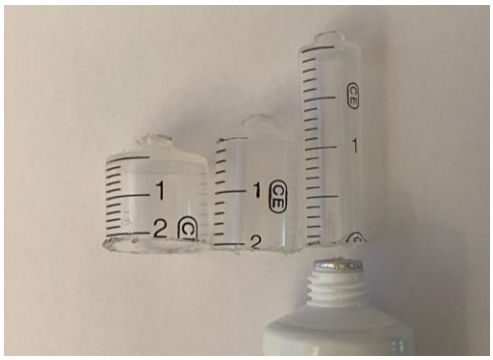

Figure 27: Tube sizes

Results:

Tacrolimus ointment - thinnest consistency	Ease of squeezing	seamless filling
Tube 1 - narrowest	6	5
Tube 2 - medium	6	7
Tube 3 - tallest	6	7

Mometasone ointment - medium consistency	Ease of squeezing	seamless filling
Tube 1 - narrowest	5	5
Tube 2 - medium	5	6
Tube 3 - tallest	5	7

Clobetasol cream - thickest consistency	Ease of squeezing	seamless filling
Tube 1 - narrowest	4	4
Tube 2 - medium	4	6
Tube 3 - tallest	4	6

Conclusion & Implementation:
From the results it can be concluded that the ease of squeezing out the cream or ointment, is not affected by the width of the tube it is being squeezed into. However, the seamlessness of the filling is affected. Contrary to prior expectations, the two wider tubes filled up more seamlessly with fewer air bubbles. Although the widest tube scores slightly higher, the medium width is taken as the most appropriate size. This decision builds on the fact that wider tube results in a flatter FTU volume, and one FTU being too flat, makes it more difficult to work with. Lastly, throughout this experiment, the challenge of cleanability was confirmed, thus highlighting the need for a cleaning kit.

6.2b Tube volume determination (FTU → Ml) - Experiment 2

Aim & Relevance: Translating FTU into a more accurate volume in ml. Although FTUs are already a unit of volume, they are of a highly inaccurate nature, making it difficult to translate them into tube sizing. FTUs are highly diverse from one hand size to another, however on average, one FTU should correspond with 0.5 mg of cream or ointment (Mekkes, 2021).

Approach: Based on the FTU rule of fist, where one FTU should be applied to an area of two corresponding hand palms (Mekkes, 2021), it can be concluded that this application method revolves around the finger-to-hand ratio within one hand size. Additionally, it is very difficult to find more accurate, elaborating measures for this methodology. To solve this, this experiment will be executed by using the researcher's own hands, while focusing on implementing the correct sizing ratios (for further details, see section 6.6).

Method: For each of the three corticosteroids, four FTUs are measured and filled into the middle-sized tube from the previous experiment. Measuring with four FTUs instead of one was a deliberate choice as this allows for a more accurate average volume as compared to using solely one FTU sample. Once the barrel/tube was filled up with four FTUs, the volume in ml was read and noted down. Then, the barrel was emptied out and the cream or ointment was weighed. This step allowed for extra validation, by comparing the actual weight to the expected weight of 2 mg (four times the average weight of 0.5 mg according to Mekkers (2021)).

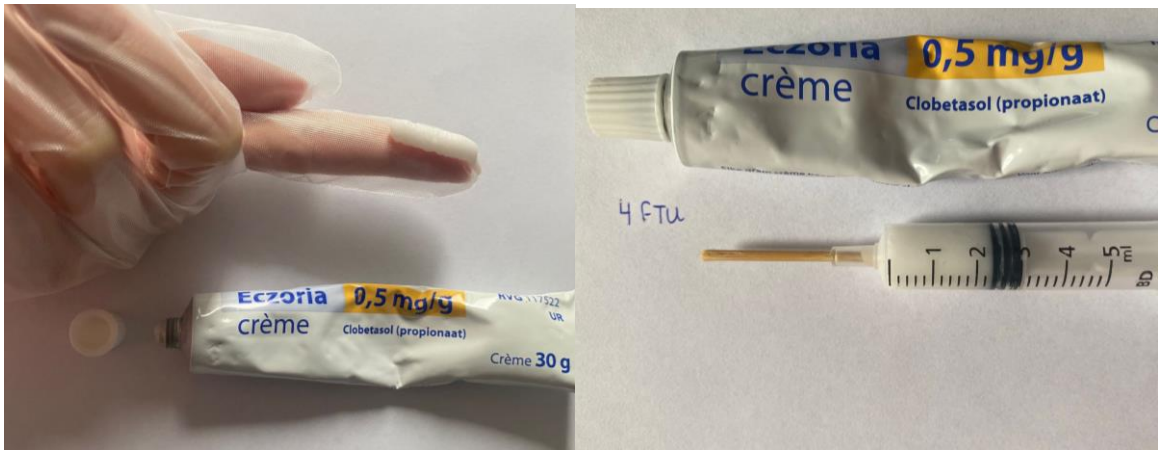

Figure 28: Tube volume determination

Materials:

- Tacrolimus monohydrate ointment - 30mg (Thinnest consistency)
- Mometasone ointment - 30 mg (Medium consistency)
- Clobetasol (propionate) cream - 30 mg (Thickest consistency)
- 5 ML syringe

Results:

4 FTU -	Tacrolimus ointment	Mometasone ointment	Clobetasol cream
Volume in ml	2.3	2.8	2.4
Weight in mg	2	2	2

Conclusion & Implementation:
The volume measurements of four FTUs for the three types of corticosteroids ranges from 2.3 to 2.8 ml. It has been repeatedly established that undertreatment is a major problem within the scope of this project. Therefore, it is assumed that the largest volume measurement needs to be chosen to prevent further undertreatment. This would mean an 'overtreatment' of 22% (0.5/2.3 * 100), for the ointment with the smallest volume. This issue was discussed with dermatology experts, who concluded that overtreatment can never really be a problem within this context, thus making this a valid decision.

6.3 3D model

The sizing experiment results were used to determine the height and width required for the design of a barrel that fits two FTUs. These measurements were found to be a width of 1.25 cm and a height of 1.1 cm. However, in practice, the barrel needs to be higher since the rubber top of the plunger also requires a height of approximately 1 cm. With these measurements in mind, the 3D models were developed.

First, the barrel element was modeled (Figure 29). Throughout the development of this model, various factors had to be considered, these are elaborated below:

First, the lid which would ideally stay attached when opened, to prevent it from being lost and improve overall ease of use. However, it is very complicated to implement such an attached lid in a 3D model or print (as confirmed by a 3D printing expert), thus for the sake of this prototype it was incorporated in the form of a detached lid.

Secondly, multiple rims were added to the barrel with diverse functionalities. The upper, outer rim (Figure 29: 'Lid Rim') is an addition that helps keep the lid in place. This rim is thus not part of the ideal form of this mechanism, which would come with an attached lid. Then, the outer rim, or 'baseline' (Figure 29), is added to point out what area of the barrel will be filled up with cream or ointment. The area below this line will be filled by the rubber top of the plunger, as can be seen in Figure 29). Lastly, the inner rim (Figure 29) is added to attach the barrel more securely to the plunger and prevent the barrel from easily being pulled off when not necessary.

Lastly, the barrel will need to include measurement lines (in FTUs), which can be added in as seen in Figure 29. These lines will be added in units of 0.5 FTU.

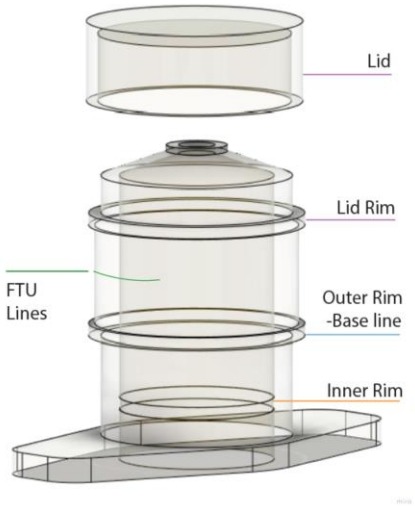

Figure 29: Barrel 3D model

Figure 30: Plunger and barrel 3D model

Building upon the measurements of the barrel, the 3D model of the plunger was created (Figure 30). This model includes the previously mentioned gripping element, to prevent unnecessary force from being exerted on the tube as the barrel is pushed down. As well as the rubber top, which ensures a better-secured attachment.

The plunger element includes extremely complex challenges, namely:

1) The exit of the plunger must be implemented in the form of a one-way valve. Otherwise, pushing down the barrel would cause the cream or ointment to go back into the tube. Unfortunately, a consultation with a 3D modeling and printing expert concluded that the implementation of this valve would not be possible in a 3D-printed prototype. Other methodologies for the implementation of this element will be explored in the final concept chapter (8).
2) To be able to attach the plunger to different types of corticosteroid tubes, the inside will need to be threaded. Initially, it was assumed that all 30 mg tubes contained the same exit measurements and lid size. This was also assumed by various experts, including dermatologists and pharmacists. However, in practice, it was found that the tube exit measurements slightly differed from one corticosteroid type to another. Therefore, the plunger will need a universal adapter that fits slightly different tube exit sizes. The possibilities for a universal solution will be left outside the scope of the 3D model, as an easy solution was not found, and complicated or detailed elements will be

difficult to implement into the 3D model. Instead, multiple possibilities will be discussed in the final concept chapter (8).

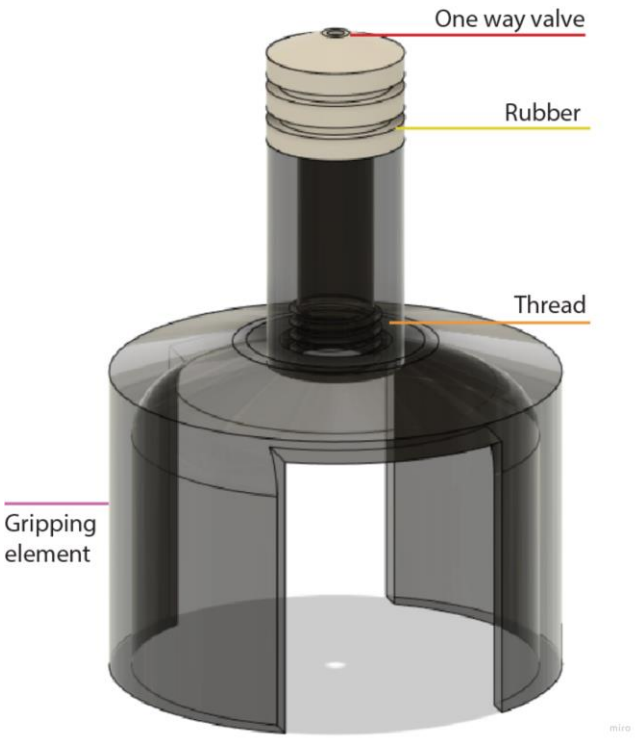

Figure 31: Plunger 3D model

Additional visualizations of developed 3D models:

Figure 32: 3D models - Showcase

6.4 3D print & evaluation

Once the 3D models were developed, they could be printed for further analysis. Prior to starting the printing process, additional research was required to determine which type of 3D printer is able to print using multiple materials, as well as transparent plastic. To tackle this, a meeting was scheduled with an expert in 3D modeling and printing. Based on that, the recommendation was to make use of PolyJet printing. During the expert meeting, various example models were shown that were produced using the PolyJet printer. This also provided the opportunity to explore different materials, their respective stiffness, and colors (Figure 33).

Within this context, polyjetting stands out as the most fitting printing method due to its extensive possibilities. It is an additive manufacturing method that allows for the simultaneous printing of multiple materials, which can result in the creation of detailed models (Patpatiya et al., 2022).

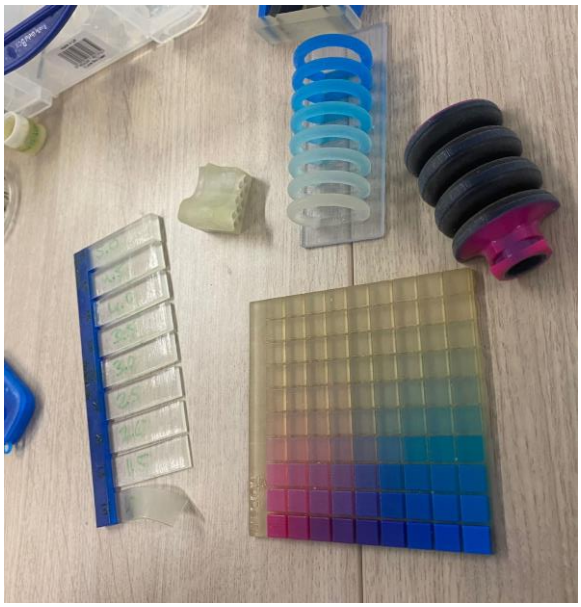

Figure 33: Examples PolyJet printed models

The 3D model was then printed to assess the concept's visual appearance and haptic properties. By creating a physical model, it was possible to further analyze and evaluate the overall aesthetics and feel of the design. Both elements of the dosing mechanism were printed, as seen in Figure 34.

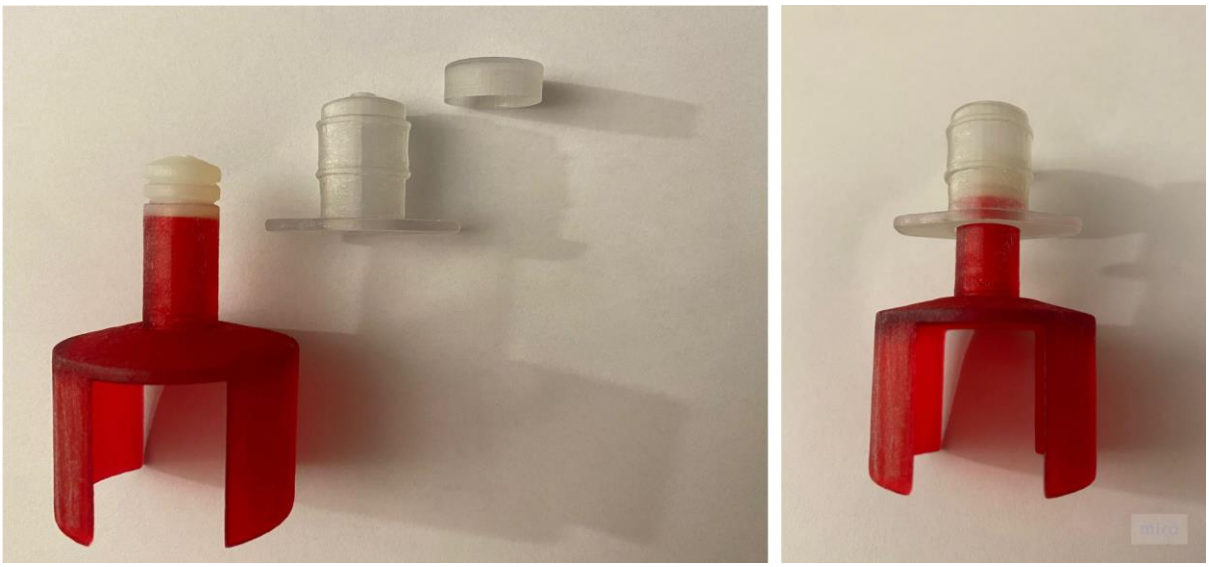

Figure 34: 3D models; Plunger, barrel & lid

Although it was initially intended, the 3D model could unfortunately not be used for functional testing. This is caused by two reasons: First, due to a calculation error, resulting in the model not fitting properly on the tube. Additionally, the lack of transparency in the model made it difficult to assess how effectively it would fill up with cream.

The 3D model was used to conduct evaluations on the tactile experience of operating the mechanism by pushing it up and down while applying force to the gripping element. The assessment considered its usability with one hand or two hands (Figure 35). Overall, the model proved to be quite comfortable during use. However, for future iterations, it is recommended to slightly increase the height of the plunger compared to the barrel to provide additional space to insert fingers and push up the barrel when it is fully down.

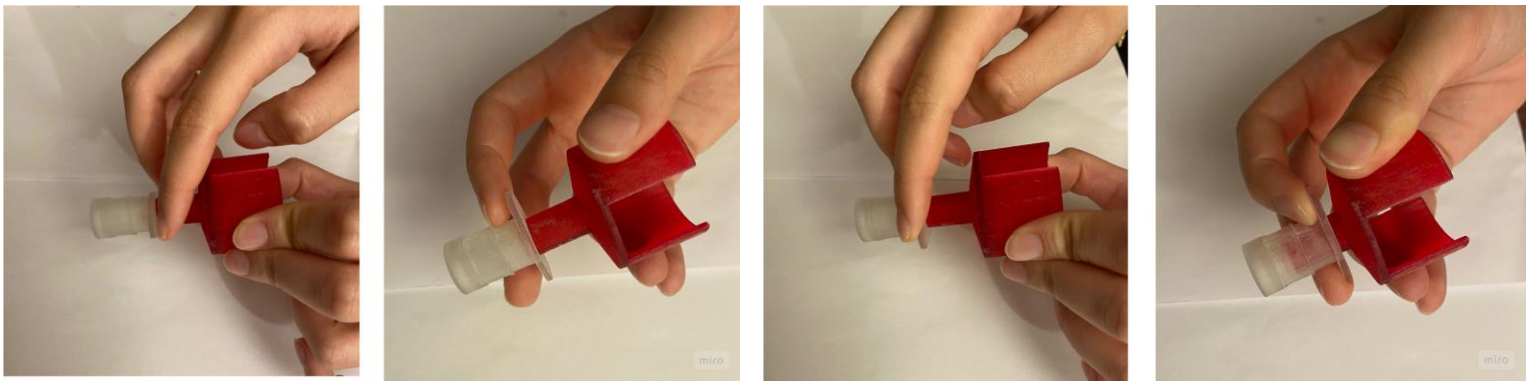

Figure 35: Exploration 3D models

Additionally, the 3D model was evaluated next to a 30 mg corticosteroid tube to assess its fitting. The examination showed the size to be appropriate (Figure 36). Moreover, this helped confirm the opening in the plunger provides enough room to squeeze the top of the tube when required.

Figure 36: 3D model ratio analysis.

6.5 Material Exploration

During the initial stage of the prototyping of the Measure Stuffy, research was conducted to identify suitable materials that closely resemble human skin. The aim was to find materials that could accurately replicate the properties observed in AE, particularly concerning the integration of diverse textures. In addition to texture, other elements that were taken into consideration were cleanability and various physical properties such as material stiffness and ease of converting it into a stuffed animal.

Leather was found to be an excellent material choice to represent both healthy skin and skin affected by AE due to several reasons. Firstly, it is widely known that leather shares certain properties with human skin, including texture, flexibility, and durability (Bai et al., 2022). Additionally, leather provides a wide variety of colors and textures, which is very useful within the context of this concept. Lastly, Leather is selected due to its good cleanability, as its smooth surface allows for the easy removal of dirt or stains with simple cleaning methods such as wiping it down with a (wet) cloth.

Another material that was taken into consideration was the 3D printing of silicone textures. The expert consultation on 3D modeling and printing confirmed the possibility of printing specific textures while combining materials with varying levels of stiffness. However, as this approach is far more complex and expensive, it is considered unnecessary for the current scope of the project. It may be worth exploring in future iterations of the product if deemed relevant by further evaluations.

At this stage, a diverse assortment of leather types was collected to initiate the evaluation process and identify textures that are relevant for the further development of the concept (Figure 37).

Figure 37: Initial leather assortment

6.6 Mock-up Prototype

In addition to the material and texture research, progress was made towards the development of an initial mockup prototype that aimed to address the sizing aspect of the Measure Stuffy. This step is crucial as it aligns with the design direction of visualizing the skin surface to which one FTU of cream or ointment should be applied. By creating a tangible visualization of the appropriate surface area, the concept aims to enhance understanding of the FTU application method. Therefore, it is essential to validate the size at an early phase of the prototyping process, which is done alongside the validation of the leather samples. When both elements have been evaluated, a new iteration of the Measure Stuffy can be developed, that incorporates both the validated size and the selected materials.

The first step, towards the mock-up prototype, involved the creation of a sewing pattern. This was achieved by using the existing method explanation, which specifies that one FTU should be applied to an area equivalent to two hand palms (Mekkes, 2021). To determine the specified hand size, average hand sizes of a Dutch adult were used, as obtained from the database on Dined (n.d.) (Figure 38).

populations	Dutch adults 20–60, mixed	
measures	mean	sd
Hand width (with thumb) (mm)	103	9
Hand length (mm)	187	13

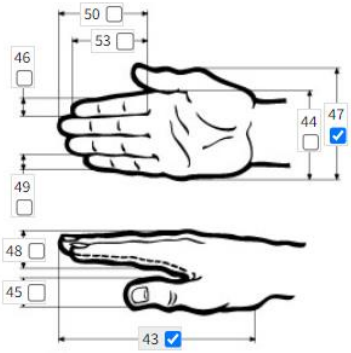

Figure 38: Average hand sizes. (DINED, n.d.).

Within the concept of the Measure Stuffy, the surface area of two hand palms needs to correspond to the body of the stuffed animal. This requirement is translated into the creation of the sewing pattern, as follows:

First, the Dined (n.d.) measurements were used to visualize the possible body of the stuffy (Figure 39). Which was then translated into a sewing pattern for the stuffed animal's body (Figure 40). The patterns for the ears, arms and legs were made to proportionally match with the body (Figure 41). However, apart from providing an enlarged surface area to integrate textures, the sizes of the limbs do not impact the functionality of the concept.

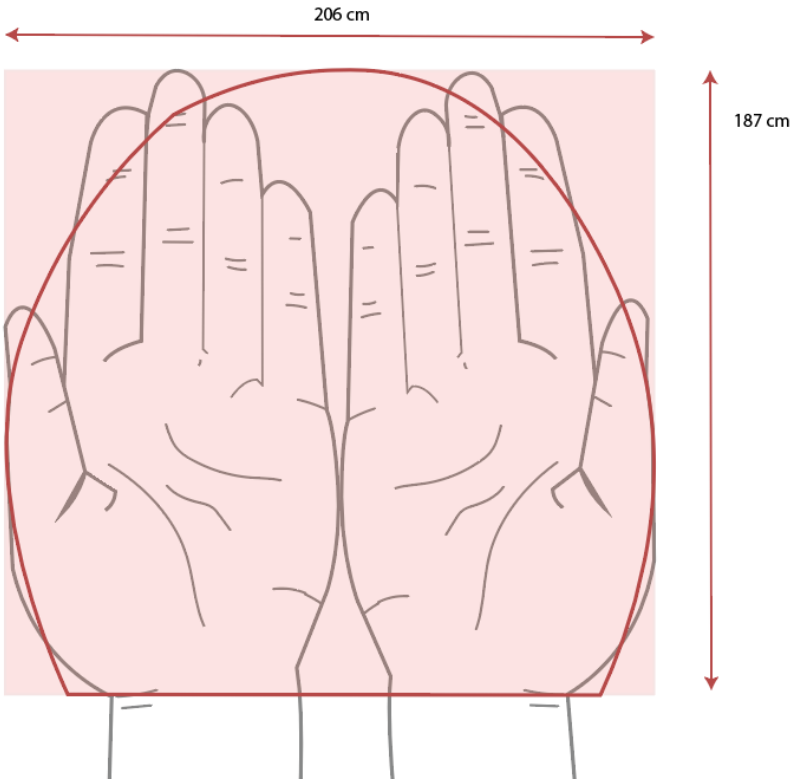

Figure 39: Reshaping hand size to body form

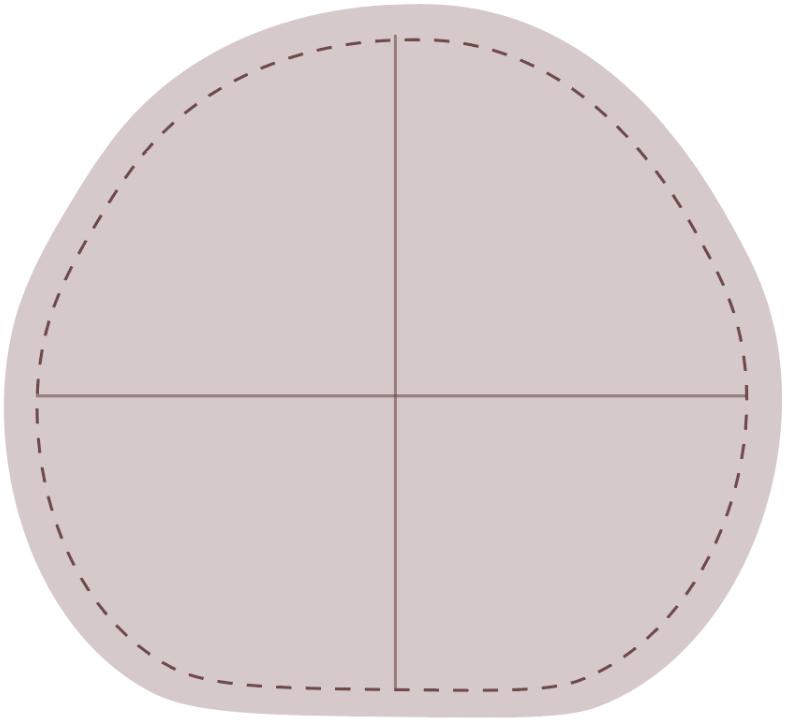

Figure 40: Sewing pattern - Measure Stuffy; Body

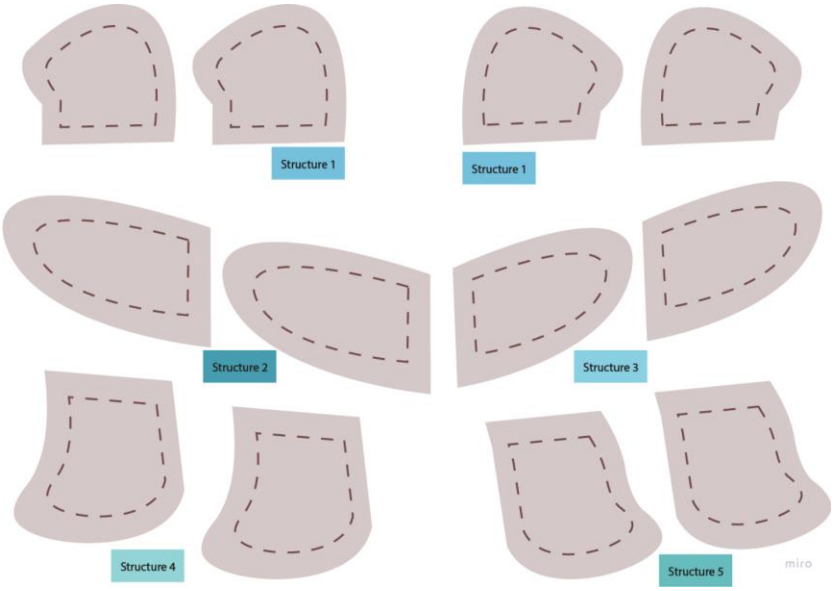

Figure 41: Sewing pattern - Measure Stuffy; Limbs.

Subsequently, a mock-up prototype of the Measure Stuffy was developed to enable its size validation through expert interviews (Figure 42). This prototype was not yet made in the relevant textures but was mainly for visual communication and evaluation of the size of the main body compared to the two adult hands.


Figure 42: Measure Stuffy - Mock-up Prototype

6.7 Textured Prototype

Building upon the material and sizing validation, the next iteration of the Measure Stuffy was developed. This iteration focused on incorporating the relevant textures, aligned with the intended functional goals of representing three distinct phases of AE (mild, moderate, severe).

Before creating this prototype, a comprehensive evaluation of new, exhaustive leather samples was conducted (Figure 43). The leather was categorized into four phases, ranging from healthy skin to heavily textured skin affected by AE.

Figure 43: Evaluation updated leather samples

The designated textures were incorporated into the Measure Stuffy as follows: The body symbolized healthy skin, the ears showed a mild AE texture, the arms a moderate AE texture, and the legs a severe AE texture. For the sake of the expert validation, it is beneficial to incorporation of more textures, to allow the expert to feel which is best. This was implemented by using different textures for the front versus for the back of the Measure Stuffy (Figure 44).

Figure 44: Second iteration - Measure Stuffy - Front & Back

Moreover, the size of the stuffed animal was adjusted in comparison to the previous iteration, which was influenced by the change in hand size as observed in experiment 6.2b (Figure 45, red dotted line). Acting on the suggestion of a dermatology resident, who recommended reducing the size by 5-10% to account for the caregiver's tendency to undertreat and apply the cream on a larger area than prescribed, the size was subsequently decreased by 7% (Figure 45, green dotted line).

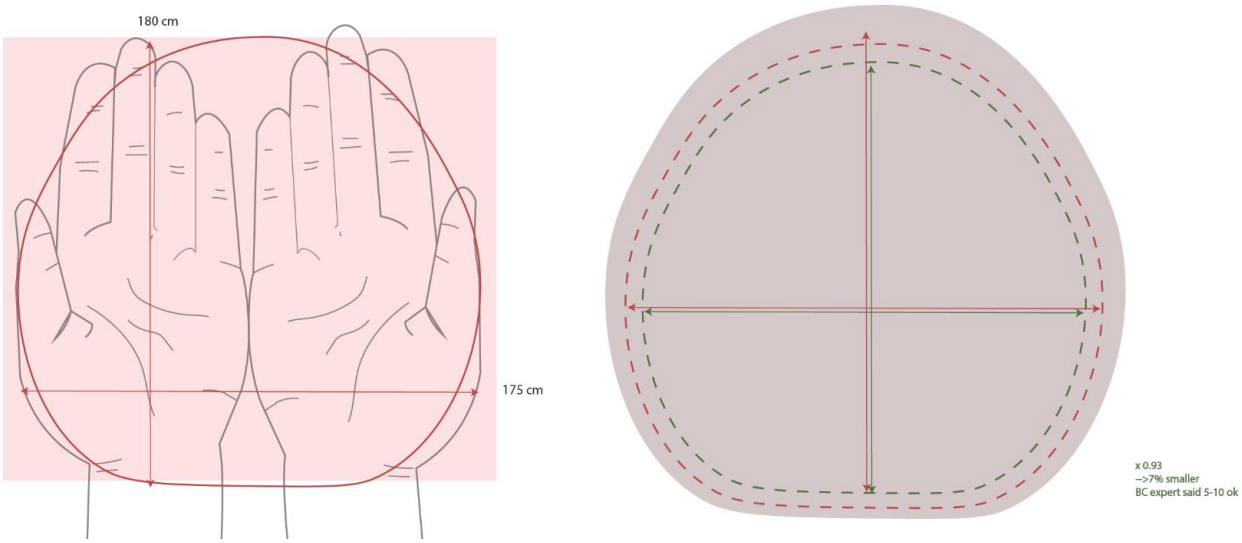

Figure 45: Adjusted Measure Stuffy sizing

Alongside the integration of textures into the Measure Stuffy, the corresponding leather samples were also cut into squares to facilitate an unbiased blind test for the experts. (Figure 46). This iteration of the prototype can now be used for the specialized expert interviews with child dermatologists (section 7.1).

Figure 46: Second prototype iteration - Measure Stuffy & additional samples

Concept Evaluation

This chapter will evaluate the concepts as per their last iterations. The evaluation will be divided according to expert feedback, user feedback and a final evaluation according to the three lenses of innovation.

7.1 Expert Validation

A total of five interviews were carried out with six diverse experts, in three distinct phases, categorized as follows:

- Two general interviews involving both concepts in their mock-up phase, conducted with dermatology residents with extensive treatment experience (7.1a).
- One interview with a pharmacist and a senior pharmacy assistant, evaluating the two options of the add-on dosing mechanism (7.1b).
- Two interviews with specialized child dermatologists, focusing on the evaluation of the concepts in their latest iteration (7.1d).

Moreover, prior to the final set of interviews, an interactive presentation was delivered to a team consisting of more than 10 PhD researchers and Postdoc's from the Erasmus MC dermatology department. The purpose of this presentation was to evaluate the defined concepts and corresponding (experiment) methodologies (7.1c).

7.1a Concept validation - Dermatology residents

In this section, the evaluation insights will be categorized based on the two distinct concepts.

First, the questions and insights relating to the dosing mechanism will be discussed. During the time at which these interviews were conducted, the two alternative mechanism options were still being considered. Therefore, the evaluation includes the comparison of both these options. Moreover, both concepts were evaluated according to first impressions, ease of use, overall functionality, added value, hygiene, and further improvement. The interview setup including the transcribed answers can be found in Appendix B1 (in Dutch).

The insights on the first (syringe-inspired) mechanism option (Figure 16) will be divided into two sections: Positive points and identified challenges:

Starting off with the positive feedback, both experts found the syringe-inspired mechanism to be a smart and accurate solution. The second expert emphasized its simplicity and user-friendliness, noting that it would help reduce mismanagement in treatment. Additionally, it was determined that hygiene is not expected to be a major concern with this mechanism. Since the tube will be in constant use, the prevention of bacteria growth should not be an issue as long as it can be securely closed to prevent airflow. Finally, it was observed that the proposed mechanism is a cost-effective solution that can easily be integrated into current treatment methodologies, starting with its introduction during doctor appointments.

Moving on to the identified challenges, various factors were taken into consideration. The first expert expressed concerns about the additional steps added to the treatment process and the potential burden it may impose. Furthermore, the ergonomic grip was highlighted as an area for improvement to enhance user comfort, along with ensuring the easy cleanability of the overall mechanism. It was also mentioned that with this concept, a standardized FTU is provided, suggesting the need for a corresponding skin surface measurement tool to be used in conjunction with the mechanism instead of relying on individual hand size. Lastly, the challenge of creating a universal adaptor that can accommodate different tube sizes was acknowledged.

The second mechanism option (Figure 17) will similarly be evaluated based on the feedback categories:

Again, starting off with the positive feedback, the first expert expressed a preference for this option, noting that it appeared simple-minded, making it easier for users to understand. Additionally, the expert appreciated the automatic pop-up feature of the mechanism, which eliminated the need for an additional interaction step. However, other than that, no significant advantages were mentioned over the first option.

Regarding the identified challenges, some of them overlap with those of the first mechanism, particularly concerning the universal adaptor, cleanability, and ergonomic grip. Furthermore, this concept was evaluated as less accurate and more challenging to fill due to its shape. The second expert also expressed concerns about its fragility and practicality.

Finally, a comparison will be made between both concepts and future recommendations based on expert feedback will be provided.

When asked about their overall preference between the two concept options, the first expert chose the second option due to its simplicity, while the second expert chose the first option due to its accuracy. Evaluating both options based on different factors revealed that both experts considered the first option to be superior in terms of functionality and accuracy. In terms of the concept's ease of use, there was a difference in opinion. And lastly, in terms of hygiene, both experts again chose the first option as the superior concept.

As for the recommended additions to the concept, two adjustments were suggested. Firstly, the option of a larger mechanism to accommodate severe AE or older patients. Secondly, providing a cleaning set to improve ease of use.

Then, the evaluation of the Measure Stuffy will be divided into positive aspects, challenges, and future implementations based on the feedback received.

The overall feedback on the Measure Stuffy concept was highly positive. Both experts were enthusiastic about their first impression, expressing how it is a unique and fun solution that is likely to be well-received by the children. Moreover, they appreciated the incorporation of tangible textures and considered this a valuable addition to the concept. The second expert believed that this addition would contribute to normalizing AE and providing the child with a ‘role model’. Both experts agreed that this concept had the potential to positively impact the treatment experience and enhance treatment adherence. The second expert even imagined a scenario where a child would say, "My arm still feels like the teddy bear's arm, so I must continue applying the cream."

While both experts appreciated the integration of textures and agreed that leather was a suitable material choice, they acknowledged the complexity of finding accurate textures that truly represent different AE textures. They emphasized that researching and developing accurate textures could be a whole project on its own, suggesting that this concept should provide initial recommendations rather than attempting to achieve the perfected texture. Another challenge highlighted during the evaluation was the consideration of skin tones, particularly if it is decided that the Measure Stuffy should incorporate human skin tones. In that case, it would be important to ensure inclusivity. Lastly, the cleanability of the stuffed animal needs to be considered to maintain hygiene standards.

Some future recommendations for the Measure Stuffy concept were given as follows:

- Implementing a traffic light method: Utilizing different colors to represent the severity of AE can provide a clear visual indicator for caregivers and users.
- Adjusting the body size: It is suggested to slightly decrease the size of the stuffed animal's body, to account for the caregiver's tendency to undertreat and apply the cream on a larger area than prescribed.

- Creating an adjusted version of the tool that tailors to the needs of older patient patients: A less playful version of the concept, for example, a board with measurements and structures, so that older patients can also use it to educate themselves.

Implementing these recommendations can enhance the Measure Stuffy concept's effectiveness while broadening its user base.

7.1b Dosing mechanisms evaluation - Pharmacists

The second set of interviews involved pharmacist experts who evaluated both options of the dosing mechanism and compared them to assist in the final decision-making. The details of the interview setup along with the transcribed feedback can be found in Appendix B2.

The feedback on the first option of the dosing mechanism can be summarized as follows. Both experts had a positive initial impression of the concept. The first expert expressed that it was a promising concept that still needed to be further developed. However, during the evaluation, several challenges were identified. Firstly, the experts emphasized the importance of considering the different consistencies of creams. They expressed concerns about whether the mechanism would be strong enough to dispense thick consistencies of cream or ointment. As a result, they believed that the previously mentioned challenges of having a universal adaptor, one-way valve, and proper gripping element were essential factors to consider in the development of the mechanism.

The feedback for the second option was considerably more negative. Both experts immediately noticed that it appeared less accurate, more fragile, and impractical. When asked to choose their preferred concept, both experts selected the first option without any hesitation.

Ultimately, the experts provided several recommendations to consider during the development of subsequent iterations of the chosen concept. Firstly, they emphasized the importance of conducting an experiment to explore the consistency of creams in a related mechanism, which eventually led to the execution of the experiment as described in section 6.2a. Additionally, they highlighted the need to explore a universal adaptor that allows for a strong enough attachment of the plunger onto the tube. As well as the need for a gripping element to prevent unnecessary squeezing of the tube, which could affect the doses. Lastly, the second expert recommended the exploration of an adjustable exit size within the plunger to enable the smooth dispensing of thicker creams or ointments by enlarging the exit. While there was some overlap with previous feedback, these new perspectives and additional points of consideration were valuable for the further development of the concept.

7.1c Interactive presentation - PhD & Postdoc's

The third form of expert validation was by the execution of an interactive presentation, for a team of PhD researchers and Postdoc's within the dermatology department. This approach proved to be simple yet effective, as it allowed for the validation of multiple experts simultaneously, with a presence of 10+ people. During this validation, the Measure Stuffy was at mock-up prototype level, while the dosing mechanism had the finished 3D models.

Overall, the presentation was extremely well received, the concepts were liked, and one of the experts started wondering out loud why such a concept is not already on the market. Compliments were given for the uniqueness and enjoyable nature of the concepts.

In addition to the validation of the concepts, a portion of the presentation focused on validating the sizing experiments for the dosing mechanism. Since the FTU method is non-accurate by nature, the corresponding experiments were also not approached with strict scientific precision. However, all experts present agreed that this approach was justifiable considering the context. It was also reaffirmed that the potential overtreatment of corticosteroids, caused by the adjusted barrel size (section 6.2b), was not problematic.

Lastly, valuable recommendations were provided for the development of future iterations. These recommendations included incorporating textured fabric squares within the Measure Stuffy to enhance its tactile experience. The cleanability and durability of the dosing mechanism were also discussed, raising questions about its lifespan and the possibility of designing it to be dishwasher safe. Furthermore, the consideration of skin colors or AE redness as part of the Measure Stuffy was mentioned again. Opinions varied regarding the added value versus the potential complexity this would introduce.

7.1d Elaborate concept validation - Child dermatologist

As a last step of the expert validation, two child dermatologists were (separately) interviewed to assess the dosing mechanism (3D model phase) and the Measure Stuffy (textured prototype phase). The focus of these interviews was the validation of the leather textures for the Measure Stuffy, thus they also included a blind test with leather swatches and a more thorough evaluation of the textured prototype. The insights gathered from these interviews will be categorized according to each concept. Please refer to Appendix B3 for the complete interview setup and selected transcribed answers.

The interview started off by an evaluation of the dosing mechanism in terms of first impression, ease of use and functionality. The first expert had a positive initial impression, highlighting its accuracy and ability to translate FTUs into tangible units. However, she expressed doubts whether the mechanism might result in a more time-consuming treatment process. In contrast, the second expert was enthusiastic about the dosing mechanism, believing it could assist in accurately dosing corticosteroids, particularly if it could be easily obtained from the pharmacist.

Reflecting more specifically on the ease of use, the first expert elaborated on her concerns about the potential for a more time-consuming treatment, which she believed required further validation, including feedback from users. The second expert, on the other hand, expressed enthusiasm about the ease of use, with her only worry being the ease of fully emptying the tube due to the presence of the gripping element that could get in the way.

All in all, both experts agreed that this tool could contribute to improved treatment adherence, particularly when children are learning to apply their own treatment. They recognized the potential value of the dosing mechanism for various types of patients.

The analysis of the Measure Stuffy focused on several key factors. Both experts had a positive initial impression, considering it a fun and useful concept. They recognized its potential to engage children from an early age and involve them in a playful approach. Regarding the size of the product, the experts emphasized the importance of ensuring that the ratio aligns with the provided FTU measurement. Additionally, the second expert suggested the inclusion of a reminder for using the stuffed animal's body as a size guide, to avoid forgetting this aspect of the concept.

Regarding functionality, both experts shared the opinion that the Measure Stuffy concept had the potential to make treatment more enjoyable and contribute to improved adherence. They agreed that focusing on textures, rather than adding skin tones, would be a more suitable approach. Caused by the fact that the addition of skin tones can be quite complicated and can easily insult certain population groups. When asked about the possibility of creating an adjusted version of the prototype for older patients, both experts expressed that they did not see a need for such a variation.

Both experts were requested to provide verbal descriptions of how AE characteristics felt based on their professional expertise. Their descriptions included terms such as dry, bumpy, crusted, and rough. Subsequently, a blind test was conducted where the experts were asked to arrange leather swatches in order of smoothest (representing healthy skin) to most textured (representing AE-affected skin). The results of both experts can be found in Figure 47. In general, the ranking of the chosen swatches closely aligned between the experts. However, it should be noted that the first expert excluded more textures and considered them as inaccurate representations of AE (Figure 47, top part).

Figure 47: Leather swatches arranged from smoothest to most textured

In conclusion, the in-depth validation of the Measure Stuffy (textured prototype) provided valuable insights. Both experts agreed that incorporating different textures was acceptable, but cautioned against labeling them as mild, moderate, or severe, as it is challenging to determine such classifications based solely on such textures. Instead, the focus should be on comparing healthy skin to AE-affected skin, with the latter being expressed through various leather textures, considering that AE expresses itself differently in each patient. Both experts concluded that additional textures such as sewing on patterns or 3D printing rough elements were unnecessary. The purpose of the texture is not to provide an exact representation of AE skin, but rather to offer different possibilities and aid in understanding how AE might feel compared to healthy skin.

Lastly, the second expert mentioned some suggestions for future advancements of the dosing mechanism. Firstly, the suggestion was made to make it more easily comprehensible for all users. By for example clear titles, and use of colors. Additionally, she mentioned how it would be highly valuable to develop a dosing mechanism that automatically adjusts to the correct dose when inputting information about the body part and age group being treated. Although this idea falls outside the scope of the current project, it is worth considering for future development and can be included in the roadmap (section 8.4).

7.2 User Validation

One of the main challenges encountered during this project was arranging user interviews, which also impacted the approach and analysis of these interviews. Initially, the plan was to interview parents of young patients with AE. However, due to limitations in participant availability, the interview setup had to be adapted accordingly. Eventually, a total of three potential users were interviewed extensively to gather their insights and validate the two proposed concepts. The interview comprised three parts: Firstly, open-ended questions about their personal experience with AE and its treatment. Secondly, a ranking exercise involving statements related to human needs. Thirdly, the evaluation of the two concepts. The detailed interview setup and part of the insights can be found in Appendix C.

The first interview was conducted with a parent who has two children who have been dealing with AE since their first year of life. The children are currently 10 and 12 years old. The second and third interviews were conducted with individuals who have experienced AE throughout their lives but have mostly outgrown it now by the age of 21.

7.2a Parent Interview

The first part of the parent interview helped reestablish treatment challenges that were previously defined through literature and observations. Furthermore, it shed light on the caregiver's approach to applying corticosteroids.

According to the parent's experience, it was easy for both children to get diagnosed with AE, after which they quickly received a treatment plan including the use of corticosteroids. When asked to elaborate on the method that was explained to them, relating to the application of corticosteroids, FTUs were shortly mentioned, but it was immediately apparent that FTUs were not part of their current application approach. Instead, this parent chose to put the cream or ointment onto their own hands, and then apply it to the AE-affected skin of their child. This method was chosen for its efficiency, as it allowed for a quicker application compared to using individual FTUs.

Various challenges relating to the treatment process were defined: Firstly, there was a requirement to wait a certain amount of time between the application of the greasy ointment and the corticosteroid. This waiting period posed a challenge in terms of managing the timing of applications. Secondly, the messy nature of the treatment process was mentioned, with the cream or ointment often ending up on the caregiver's hands, resulting in product waste.
Over the years, this parent developed a good understanding of AE and its characteristics. They were thus able to assess the condition of the skin through touch and make informed decisions about when to reduce the corticosteroid doses. However, even then flare-ups can occur unexpectedly at any moment, requiring an increase in the dosage again.

Additionally, the parent mentioned the challenge of keeping track of the number of corticosteroid tubes used on a weekly or monthly basis, particularly when dealing with chronic AE. They emphasized that the use of FTUs is only practical for treating small areas of the skin and not feasible when applying corticosteroids to the entire body. This highlights the need for a more efficient and accurate method of measuring and managing the dosage of corticosteroids for larger treatment areas.

The second part of the interview involved ranking various statements to gain insight into the overall experience of the parent within their current treatment journey and understand the underlying reasons. The parent was presented with four statements related to autonomy, followed by an assessment of competence, relatedness, and reasons for adhering to treatment.

In general, the parent provided high scores for all autonomy-related statements, reflecting their sense of control and confidence in managing their child's AE treatment. When it came to assessing competence, the parent ranked the statements slightly lower, particularly those statements relating to the factor of everyday and long-term adherence to treatment.

The relatedness scores indicated that the child generally manages and deals with their AE well, although they can sometimes face challenges in integrating it into daily activities like sports. While analyzing the reasons for adhering to treatment, one significant motivation is to improve life comfort as well as address the child's feelings of self-consciousness about their skin.

In the final evaluation, both concepts received high praise. The parents found the FTU concept to be clever and efficient, and they were satisfied with the proposed sizes, seeing no need for an additional size. They also expressed a preference for keeping the description in FTU rather than ml, as ml measurements could potentially encourage overly meticulous parents to obsess over precise measurements.

Furthermore, the Measure Stuffy concept was also extremely well received. They mentioned its significance for children aged zero to ten, as it can engage them in their own treatment process. However, they also suggested the development of an alternative concept, such as a board-like tool, for children over the age of ten. This alternative concept could be highly valuable in assisting older children in learning to carry out their own treatment.

Overall, the parents expressed great enthusiasm for both concepts and believed that they would be valuable additions to the treatment process, particularly during the initial stages when there is a lot to adapt to.

7.2b Young Adult Patient Interviews

Both interviewed participants were currently 21 years old, and initially diagnosed with AE during their first life year. Furthermore, currently have their eczema managed. The second participant still uses corticosteroids to do so.

The interview consists of the same three parts that are mentioned in the previous section. First, the common experiences in existing treatment methodologies and approaches were analyzed. The first participant shared how she felt that she could have received more explanation on her treatment options, as well as a more thorough reflection when treatment plans do not function as intended. This would have helped her understand in what ways she could ensure proper outcomes. The second participant mentioned a similar point, sharing the fact that she believed the dermatologist could have done more to research the reasons behind her severe AE and corresponding flare-ups.

While speaking to both participants, it was clear that neither of them applied FTU in their application approach. They did both recognize the term but were not able to explain its working. The first participant mentions how she would have valued a more elaborate explanation of this methodology along with other distinct treatment plans, instead of relying on her own understanding and making dosage adjustments based on perceived needs.

The statements were again ranked to get a better understanding of the participants' feelings of autonomy, competence, relatedness and reasons for adhering to treatment. Both participants scored low on the statements relating to autonomy, with scores ranging from 3 to four. This aligns with their expressed needs for better understanding of treatment and options. As for the statements relating to competence, the first participant answered them while

reflecting on the times when she fists started applying corticosteroids by herself, thus leading to lower scores. While the second participants answered the statements as per her current state where she can manage her AE and thus scores the statements higher. The relatedness again shows the need for patients to be supported better in learning to deal with AE and integrating it into their everyday life. And lastly, the element of feeling ashamed of their skin was also established.

Lastly, the participants were asked to share their opinions on the two proposed concepts. Both participants were very enthusiastic about the concepts. The first participant was surprised to see how the combination of concepts tackled her exact pain points. Additionally, both participants mentioned how having the Measure Stuffy would have helped increase their feelings of relatedness in their younger days. Lastly, the concepts would help the patients feel more confident and competent to adhere to treatment as prescribed, especially when first starting to apply treatment by themselves without support of their caregiver.

7.3 Lenses of Innovation

In addition to the evaluation from expert and user perspectives, the concepts were analyzed according to the three lenses of innovation, which considers the concept's: Desirability; wanted/needed by people. Feasibility; capable of being carried out. Viability: the concept is cost-efficient or profitable (Jeffries, 2016).

Firstly, the desirability is well established through the concept validation by both potential users and experts. Firstly, patients shared how this concept closely aligned with their struggles and would significantly help improve their experience within the AE treatment process (section 7.2b). Additionally, the concepts were established to closely solve the problem statement as per definition of experts. As experts mention, the concepts will allow for a more accurate application of corticosteroids, as well as contribute to bettered treatment adherence (section 7.2a).

The assessment of feasibility differs for both concepts. In the case of the Measure Stuffy, if the concept is assumed to focus on distinguishing healthy skin from AE-affected skin without specific texture classification, feasibility would score well. This would involve sewing a leather teddy bear, which is highly feasible using leather adjustment equipment. On the other hand, the feasibility of the dosing mechanism is slightly more complex. Challenges arise from the required strength and the incorporation of a universal adaptor and one-way valve on the plunger. A more accurate ranking of the corresponding feasibility will only be possible through the development of higher fidelity prototypes that can be used for functionality testing.

Lastly, both concepts are evaluated in terms of viability. For the Measure Stuffy, the cost of real high-quality leather could be a factor to consider. However, since the focus is on distinguishing between healthy and AE-affected skin rather than using luxury leather, the need for highly accurate, expensive materials is reduced. In contrast, the leather representing healthy skin should be accurate in likeness to healthy skin, however various options were already deemed possible from the explored leather samples. The cost numbers will highly depend on quantities, and more specified decisions regarding the chosen textures. Regarding the dosing mechanism, it demonstrates high viability, as it can be developed using materials and

techniques like those used for syringes. Syringes are readily available at low costs, further enhancing the feasibility and viability of the dosing mechanism concept.

Final Design

within this chapter, the final design iteration is proposed while considering evaluation results from the previous chapter. This chapter also allows further analysis of the concepts through future recommendations and a proposed client roadmap.

8.1 Current Iteration

Within this section, the latest version of both concepts will be highlighted, as adjusted by considering part of the validation findings.

8.1a Dosing element

The general dosing element will not be changed much in size as compared to the 3D printed model. As mentioned, one adjustment is providing extra space between the barrel and plunger, to make it easier to push up the barrel from the fully lowered state.

Furthermore, possible solutions were identified for the two main challenges of creating a universal adaptor and the addition of a one-way valve to the plunger's exit.

As for the universal adaptor, three possible solutions are proposed, which should be further evaluated in the next steps of product development.

1) Design the inside thread of the plunger, such that it is slightly cone-shaped. The wider tube exit could thus be attached right at the bottom/the widest part of the cone. Whereas the smaller tube exit will be turned to fixation slightly deeper into the threaded inside. This solution is only possible if the tube sizing differs to a slight extent, as with the three tubes used throughout this project. However, if it is established that the inclusion of other corticosteroid tubes leads to a wide variety of sizes, this solution would not be suitable.
2) Designing the inside of the plunger to be slightly wider than the (biggest) tube's exit. And then adding in a narrower, flexible material such as rubber. Which will safely secure the narrow tube exit and be slightly pushed in to secure the wider tube exit. Ideally, this concept is also only executed when the tube exit sizes do not vary to a great extent.
3) Designing separate adaptor elements for each distinct tube size, that all fit into the same plunger thread. The instead of this mechanism would be customized to the tube's exit, while the outside will be standardized to fit the plunger element. This solution should be further explored in the case that the tube exit sizes greatly vary.

As for the addition of a one-way valve, inspiration is taken from a ketchup bottle (Figure 48). Which has an extremely simple one-way valve made of flexible material. It is assumed that

such a solution will be sufficient in the context of the dosing mechanism, as the pressure difference will cause the ointment or cream to be pushed outside the barrel, instead of forcing itself through this valve in the opposite direction.

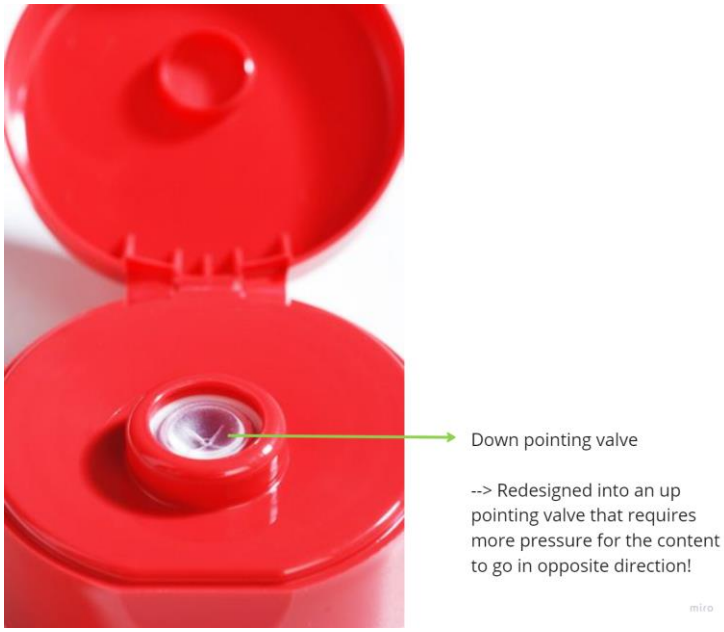

Figure 48: Explanation of integration ketchup valve

Overall, the general looks of the mechanism will stay almost the same, with measurement guidelines in units of 0.5 FTU are added to the barrel. An example of the corresponding visualization can be seen in Figure 49. As priorly decided, the product will be provided in two sizes; one that can contain up to 2 FTUs and another one that can contain up to 5 FTUs. The product will also come with a set of barrel cleaning and drying brushes (Figure 19).

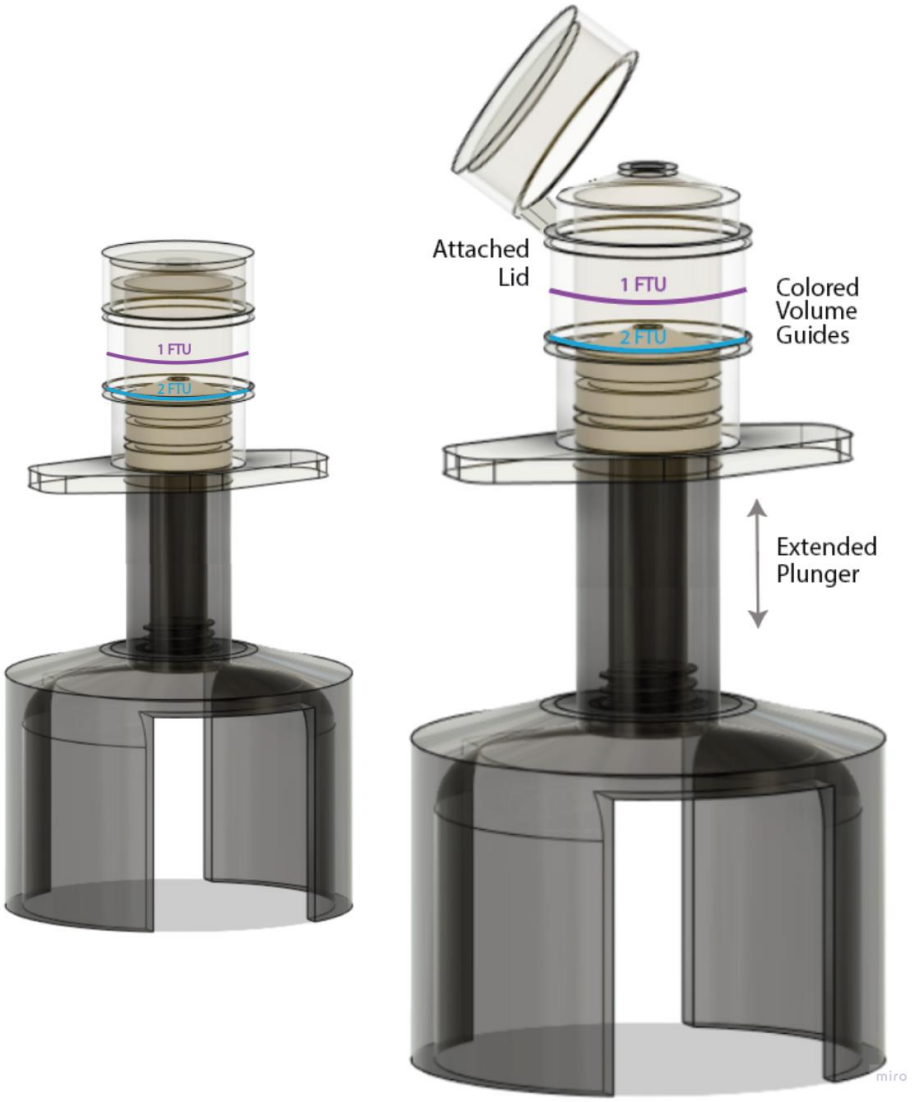

Figure 49: Visualization final mechanism proposal

8.1b Measure Stuffy

In contrast to the dosing tool, the Measure Stuffy was adjusted on concept level based on the given expert feedback. The concept was adapted regarding the integration of textures. Both specialized child dermatologists, empathized to not label the textures from mild to severe, but instead only provide the comparison of healthy skin versus different expressions of AE texture. Although the essence of the concept is changed, the integrated textures can remain quite the same. The first rounds of expert validation warned not to include too many textures, as this could get confusing to understand for both the caregiver and patient. However now that the function of adding in textures is to symbolize the various forms of AE, it could be quite valuable to play around with the implementation of diverse textures. For example, the final product could, like the textured prototype, have different textures on the front versus the back of the limbs. Or the bettered version of this; is to provide each individual limb with its own texture.

Next to the integration of textures, varying input was received regarding the integration of color. According to most experts, colors should not be included in a sense that they match human skin tones. Since it will add an extra layer of complexity to make these colors adhere to the actual expression of colors on various skin tones. However, from the user and patient perspective, it was shared that for them the addition of colors to any extent would add value to the overall experience. Example given, by seeing red spots on the teddy bear, the child can feel comforted and not alone in this. To find a middle ground in this, the concept will play around with non-skin like colors, which will have the integration of different darker or lighter patches. Some red patches can also be included here and there.

Figure 50 shows how the combination of colors and textures can be integrated playfully, while also adding in additional colored spots to help further improve the child's relatedness. Ideally, the body of the stuffed animal would also be a more colorful, smooth leather. Other than that, no changes are made to the Measure Stuffy concept, its size will remain the same as it was validated to be appropriate.

Figure 50: Proposed Final Visualization - Measure Stuffy

8.2 Future Recommendations

In addition to the feedback points considered for the adaptation of the final concept proposal, a lot of findings and discussion points can still be further explored. Within this section, these aspects will be elaborated in the form of future recommendations according to the different concepts.

8.2a Dosing Mechanism

For the concept of the dosing mechanism, further testing with high-fidelity prototyping is essential. This will allow the analysis of the concept's feasibility and overall functionality with different cream or ointment consistencies.

To be able to create a more accurate prototype, it is recommended to the development of the mechanism through injection molding. Which would eventually also be useful for market production. Through the methodology, it will also be possible to explore the integration of the one-way valve.

As for the decision on the universal adaptor, the first step lies in researching the tube exit size while considering all relevant corticosteroid tubes. Depending on the result, one of the three suggested solutions as per section 8.1a can be further explored. Ideally, it would be one of the two first solutions since a separate adaptor wastes material and is easy to lose. When comparing the first two options, the sturdiest solution should be picked. Testing of both solutions will be required to determine the superior element.

Furthermore, it is recommended to further explore the implementation of colors, to make the mechanism more playful and easier to understand for all users. For example, for each FTU of volume, the outside of the barrel can be colored in a designated color. These colors could then also be used in the treatment plans that refer to amounts in FTU.

Throughout all explorations recommended, it is important to consider the user's perspective through continuous validation. When the final decision has been made regarding materials, and development method, expected durability should be taken into consideration. This can then be translated into the maximum amount of time that one dosing mechanism should be used before it is thrown away.

8.2b Measure Stuffy

Compared to the dosing mechanism, the Measure Stuffy requires fewer immediate next steps. The concept has undergone multiple iterations and has been validated by both experts and patients or caregivers. As mentioned in section 8.1b, new adjustments have been made to the core of the concept, it is thus important to evaluate these adjustments with experts and users to determine if any further iterations are necessary.

While progressing towards commercializing the Measure Stuffy, the focus should be on further exploring materials and texture integrations. The textures need to be evaluated according to durability, cleanability, look and feel. There is no need to reiterate the concept's size, instead the overall concept needs to be re-evaluated. If further evaluations suggest additional adjustments, they can be incorporated while working towards the final product.

8.2c Other Concepts

Throughout the design process, other concepts were also considered in addition to the dosing tool and Measure Stuffy. One of these concepts directions was the development of a behavior tracking tool, which was introduced in section 5.3.

The tracking tool serves multiple purposes. Firstly, it facilitates the communication of treatment behavior back to the dermatologist during check-up appointments. This enables a better understanding of the treatment progress and any necessary adjustments. Additionally, the tracking tool allows caregivers or patients to monitor the number of corticosteroids used on a monthly or weekly basis, while reflecting on how it corresponds with the expected amount. Furthermore, the tracking tool can be designed in a fun and playful way, aligning with the design vision of enhancing the overall treatment experience and promoting child to carer bonding.

Overall, the tracking tool concept direction demonstrates valuable benefits and should be further explored in the project's development. In particular, the tracking bin shows promising value due to its broad functionality. It tackles both daily tracking behaviors, and longer-term tracking behavior through the collection of emptied tubes. By keeping track of the empty tubes, awareness is raised regarding the amount used and communication back to the dermatologist is facilitated. As an alternative, a simplistic tracking tool concept can also be explored. For example, standardized sticker sheets, which the child could easily bring along to check-up appointments. Such concept could help in behavior tracking, however, would score significantly lower on enjoyability and stimulation of bonding and thus the overall contribution to the design vision.

In addition to the tracking tool, a more futuristic exploration could lie within the development of an overarching phone application. This app would contain additional information on the full set of tools, while also acting as a digital diary to track the patient's AE while considering flareups and challenges in treatment.

8.2d General Advice

General points of advice, regarding mindset and approach in communications, are provided to the client as the following recommendations:

- Acknowledge and address the barrier of child resistance: Recognize the importance of acknowledging and addressing the concerns of child resistance to support and validate caregivers.
- Explain underlying reasons for treatment recommendations: Based on the patient interviews, it is advised to consciously explain the underlying reasons behind certain treatment recommendations or methodologies to improve patient understanding.
- Address corticophobia: Acknowledge and discuss the relevance of corticophobia, naming the problem and spending time addressing its severity, can help alleviate fears and reduce undertreatment.
- Remind patients of the fluctuating nature of AE: Since AE is a chronic condition, treatment experiences can be tiring and lengthy. It is important to regularly remind patients about the fluctuating nature of the disease, providing reassurance and improving persistence in adherence.
- Promote the "reward from results" mindset: Focus on and acknowledge positive results to motivate and reassure patients. By highlighting improvements, patients can be encouraged to persist in their adherence to treatment.

These recommendations aim to enhance communication, understanding, and motivation for both caregivers and patients throughout the treatment process.

8.3 Roadmap

Within this section, a timeline integration will be provided including the recommended next steps as per section 8.2.

In the initial phase of development (0-6 months), the primary focus should be on the next steps outlined for the dosing mechanism and measure stuffy. Building upon the findings and proposed concepts from this report, the development of the finalized version of both concepts should be achievable in six months.

After that, beta testing can be conducted to assess the concepts in real context and identify any issues prior to the general, commercialized release. This phase also provides an opportunity to simultaneously explore additional concepts.

Based on beta testing results, the products can be adjusted where needed, and the introduction of new supportive tools can take place (tacking tool and perhaps simple app).

Following that, the continuous improvement cycle begins, where the products will be adapted to incorporate new technical and scientific advancements. In the next five to ten years, a possibility might emerge, to integrate modernized AI technologies to further develop such supportive tools in a more instinctive and easily comprehensible way.

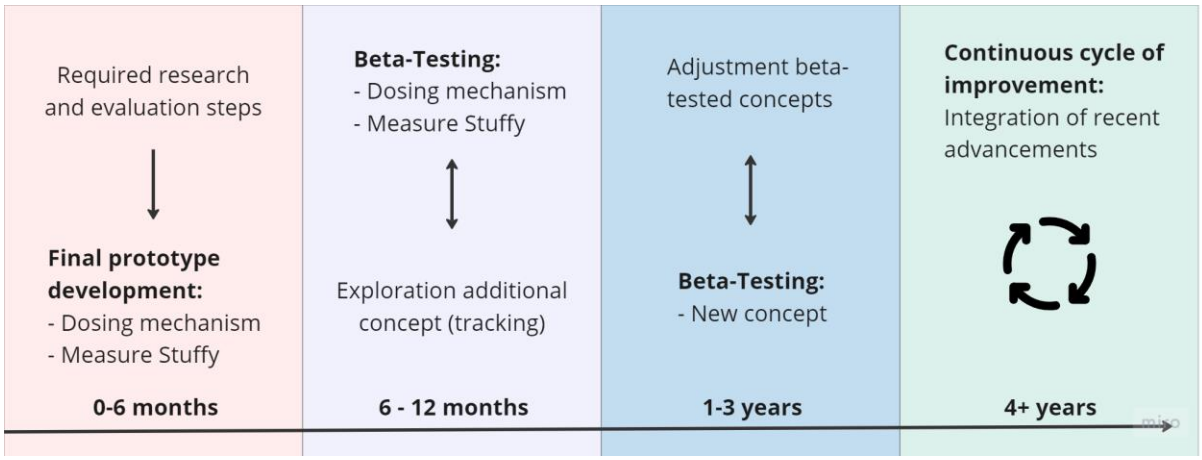

Figure 51: Suggested Road map

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Appendix