EECS 497 Assignment 3: User Requirements Document
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Arleen Cheema (akcheema), Evelyne Lee (evelee), Asha Rajagopal (adrajago), Lorena Sierra Reyes (lrsierra), Sarah Wirth (swirth)

Project Context, Expected Deliverables, and Scope

Project Context

Our application is a mobile application designed to empower parents of young children (under six years old) to confidently and safely manage their children's medication. Many parents struggle with calculating correct dosages, especially when information on medicine labels is insufficient for young children. This can lead to confusion, delays, misuse, and potentially serious health consequences. The main benefits of our application, as well as our expected users and stakeholders, are outlined below.

Main benefits:

I. Improved Child Safety: Reduces the risk of medication errors by providing clear dosage guidance based on Clark's Rule and weight, directly addressing the common issue of confusing or insufficient information on drug labels.
II. Increased Efficiency: Eliminates the need to wait for a doctor's response to basic dosage questions and ensures children receive the right medication quickly, helping them recover faster.
III. Cost Reduction: Prevents parents from purchasing inappropriate or unsafe medications for their children by providing clear guidance upfront.
IV. New Market Opportunity: Over time, as the reputation of our app increases, it may open up potential partnerships with pharmacies, pediatricians, or telehealth services, creating new market opportunities in the digital healthcare sector.

Stakeholders being considered:

I. Primary Users: Parents and caregivers of children under six years old, especially first-time parents who may be particularly anxious about medication safety.
II. Secondary Users: Grandparents, babysitters, nannies, and other individuals responsible for administering medication to young children.
III. Regulatory Agencies (e.g., FDA): Oversee medication safety guidelines and labeling requirements, ensuring regulatory compliance.
IV. Pediatricians & Healthcare Providers: Doctors who advise parents on medication safety could reference or integrate this tool into their guidance. They also may be indirectly impacted by parents turning to the app instead of calling for assistance.

Potential Future Stakeholders:

V. Pharmacies/Pharmacists: May have an interest in integrating or promoting the tool as a resource for customers.
VI. Healthcare & Digital Health Companies – Potential competitors or partners offering similar tools or services in the healthcare space.

Expected Deliverables and Scope

Our most important deliverable will be the app itself, specifically its ability to provide clear, accurate, and accessible medication guidance for parents. This includes features such as dosage recommendations, safety warnings, and an intuitive user interface that simplifies complex medication information. Ensuring the app is user-friendly and trustworthy is our top priority, as it directly impacts its effectiveness in preventing medication errors

Potential stretch goals include integrating a barcode scanning feature for quick medication identification and adding AI-powered symptom-based recommendations, as outlined below.

I. In Scope (Primary Focus)
   A. Medication Guidance App Development: Creating a mobile app that provides clear and accurate medication guidance for parents.
   B. Dosage & Safety Information: Implementing a database of medications with child-specific dosage recommendations and safety warnings.
   C. User Interface & Experience: Designing an intuitive, user-friendly interface that allows parents to quickly find relevant medication information.
   D. Basic Search Functionality: Enabling users to search for medications and view dosage guidelines.
   E. Regulatory Compliance Considerations: Ensuring the app aligns with FDA guidelines and other relevant regulations on medication safety.

II. In Scope (Secondary Focus/Stretch Goals)
   A. Barcode Scanning for Quick Identification: Allowing users to scan medication packaging to retrieve relevant dosage and safety information.
   B. AI-Powered Symptom Checker: Integrating an AI-based tool to suggest medications based on common symptoms (while clarifying that it is not a substitute for professional medical advice).

III. Out of Scope
   A. Real-Time Medical Diagnosis: The app will not provide medical diagnoses or prescribe medications; it is intended for guidance only.
   B. Regulatory Certification & Approval: While the app will follow general guidelines, obtaining official FDA or other regulatory approvals is beyond the project scope.
   C. Full EHR/Pharmacy Integration: The app will not directly integrate with hospital electronic health records (EHRs) or pharmacy management systems due to complexity and security concerns.
   D. Multilingual Support at Launch: While translation features could be explored in future iterations, the initial version will be available in English only.

Background Context

Medication errors among young children are a significant concern, often caused by unclear dosage instructions on drug labels. Many medications lack precise guidance for children, leaving parents to interpret vague instructions or rely on healthcare providers, which can lead to confusion, delays, or accidental misuse.

Preliminary Research

Studies have shown that parents frequently struggle with dosing liquid medications correctly, leading to under or overdosing. A study published in Pediatrics found that over 40% of parents made dosing errors when using common over-the-counter medications.

I. Regulatory Gaps: The FDA has recognized issues with pediatric labeling, as many medications simply state “consult a doctor” without further guidance.
II. Market Gap: Existing medication tracking apps primarily focus on reminders rather than providing detailed, child-specific dosing guidance.

Technologies

A. Flutter: We will use Flutter as our primary framework for app development, allowing us to build a cross-platform application for both iOS and Android efficiently. Flutter's widget-based architecture ensures a smooth and customizable user interface while maintaining performance.
B. Firebase: For backend services, we plan to use Firebase to manage authentication, real-time database storage, and potentially cloud functions for handling user queries.
C. Trello: Our team will use Trello for task management and workflow organization. This will help us track progress, assign tasks, and ensure that each team member is contributing effectively. It also directly connects to our GANTT chart.
D. Figma: For UI/UX design, we will use Figma to prototype and refine the user interface before implementation.
E. GitHub: Version control and collaboration will be managed through GitHub, allowing seamless integration of individual contributions and code reviews.

Research methods

A. Competitor Analysis: We will study existing medication guidance tools and healthcare apps to identify strengths, weaknesses, and differentiators for our app.
B. Regulatory Review: Our team will research FDA and other relevant guidelines to ensure our app follows best practices for medication safety information.
C. Usability Testing: Iterative usability testing will be conducted to evaluate the app’s ease of use, clarity of information, and overall user experience

Algorithms and Solution Concepts

A. Dosage Calculation Algorithm (Clark's Rule)
    a. Uses weight- and age-based dosage recommendations from reputable medical sources.
    b. Incorporates a lookup table for common over-the-counter medications with verified dosage information.
    c. Implements an interpolation function to estimate correct dosages for weight ranges not explicitly listed.
B. Decision Tree for Medication Safety Warnings
    a. Determines whether a medication is safe based on child age and known medical warnings.
    b. Flags potential interactions or contraindications based on the child's health conditions (if provided by the user).
    c. Displays warnings if professional consultation is recommended before use.
C. Reminder & Scheduling Algorithm
    a. Enables users to set reminders for medication doses at appropriate intervals.
    b. Prevents accidental overdosing by enforcing required time gaps between doses.
    c. Optionally integrates with a calendar system for tracking long-term medication use.

<u>User demographic information</u>

Our app is targeted at parents of young children 0-6.

<u>Similar Solutions and Competitive Products</u>

A. WebMD Baby & Children's Health Section
    a. Description: Offers general medication safety guidelines, dosage charts, and symptom checkers for children.
    b. Limitations: Does not provide personalized dosage recommendations based on weight and age; lacks an interactive or real-time query feature.
B. InfantRisk Center App
    a. Description: A paid app developed by Texas Tech University Health Sciences Center that provides medication safety information for breastfeeding and pregnant mothers.
    b. Limitations: Focused on breastfeeding mothers rather than general pediatric medication safety; lacks dosage calculation functionality.
C. Tylenol & Motrin Dosage Charts
    a. Description: Manufacturers like Tylenol and Motrin provide printable dosage charts for their products based on weight.

b. Limitations: Limited to their specific medications, does not cover a broad range of over-the-counter and prescription drugs, and lacks real-time user input functionality.

Relevant Academic Literature

Since our project focuses on pediatric medication safety and dosage guidance, reviewing academic literature and regulatory guidelines will be essential. Below are key areas of literature and FDA resources that may be relevant to our work:

A. Pediatric Medication Safety & Dosage Accuracy
    a. "Pediatric Dosing Errors and Safety Measures" – This study highlights common dosage errors in pediatric medicine and suggests best practices for reducing miscalculations (Center for Drug Evaluation and Research, 2023).
    b. "Weight-Based vs. Age-Based Pediatric Dosing: A Comparative Study" – Explores the effectiveness of different dosage calculation methods and their impact on patient safety ("Weight-Based vs. Age-Based Pediatric Dosing," 2007).
B. Parental Challenges in Medication Administration
    a. "Understanding Caregiver Medication Errors in Home Settings" – Examines the most common mistakes parents make when administering medicine to young children and potential interventions (Ghassab-Abdollahi et al., 2024).
    b. "Health Literacy and Medication Safety in Pediatrics" – Investigates how parental health literacy affects their ability to correctly follow medication instructions (Center for Drug Evaluation and Research, 2016).
C. FDA Guidelines & Regulatory Considerations
    a. FDA's "Best Practices in Pediatric Medication Labeling" – Outlines the regulatory standards for pediatric drug labeling and recommendations for improving clarity (Center for Drug Evaluation and Research, 2020).
    b. "FDA Pediatric Dosage Guidelines for Over-the-Counter Medications" – Provides official FDA guidance on dosing recommendations for common pediatric medications ("FDA Pediatric Dosage Guidelines," 2015).

Professionals we may want to consult about our project include pediatricians or professionals in early childhood medicine. As of now, we are unsure whether this will be necessary.

User Requirements

User Requirement	Relative Priority	Specification	Measurement Methodology	"Not-you" Requirement
Accurate Dosage Calculation	5	99% accuracy based on Clark's rule when compared to a dataset of pediatric dosages	Compare app calculations with a dataset of pediatric dosages including at least 20 varying cases.	Yes, no one in our team regularly needs to calculate dosages for children.
Accurately predict drug interactions	5	Identify potential interactions for at least 90% of common medication combinations for children under six.	Compare our database to a comprehensive list of common medication combinations taken by children and their interactions.	Yes, no one in our team regularly needs to predict drug interactions for children
Comprehensive Medication Information	5	Includes information on common 90% of childhood medications (dosage, administration, side effects, warnings)	Compare our database to a database of commonly prescribed medications for children under six.	None of us are children under the age of 6 taking these medications.
Medication Checklist Reset	3	The medication checklist will automatically reset 24 hours after the last item is checked, or when the medication is no longer in effect.	Repeatedly set a timer and check to ensure that the checklist is reset after a certain amount of time. Do this for varying medications.	None of us take medication on a timed basis
Intuitive User Interface	4	An average task completion time under 60 seconds	Record and time user testing. Also, consider qualitative feedback through user experience	N/A

Figure 1. User Requirements table outlining requirements we aim to achieve during this phase of development.

Project Management Strategy and Plan Update

Our initial project management strategy remains largely the same. We will continue using GitHub, Trello, Figma, and Apple messaging for communication and project management. We have identified Flutter and Firebase as our primary development tools and are dedicating time to learning these technologies. Our team responsibilities and roles also remain the same, and are outlined below and in our GANTT chart.

<u>Team responsibilities and roles:</u>

- Medication Comparison and Interactions: Asha, Sarah
- Medication tracker: Lorena, Evelyne
- Dosage checker: Asha, Arleen
- Integration of parts/Administrative work: Sarah, Arleen
- UI/UX: Lorena, Evelyne

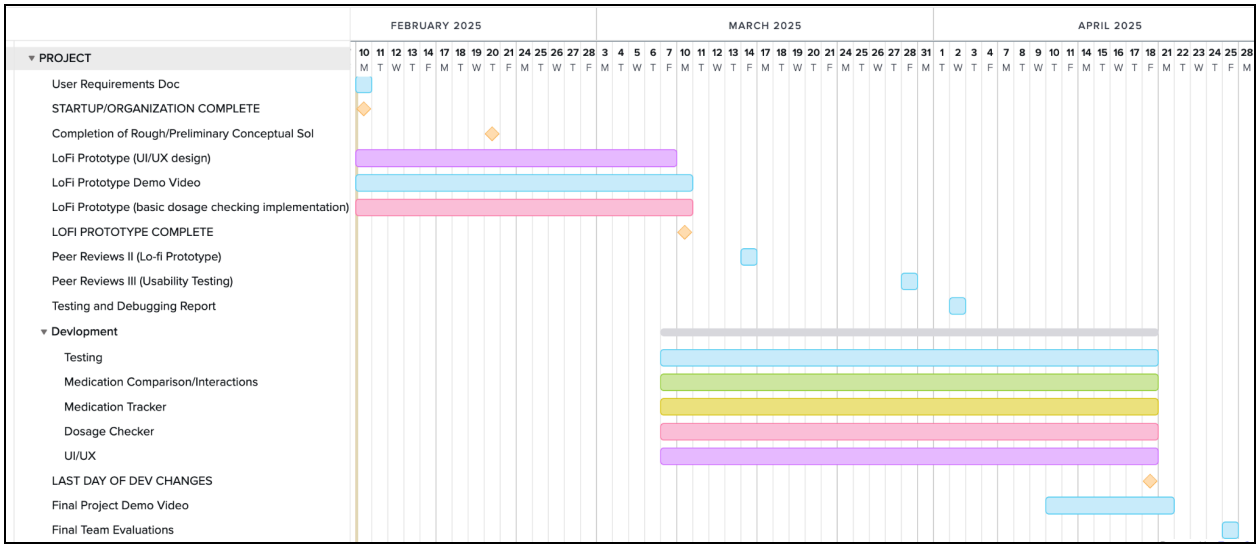

Figure 1. GANTT chart created using our Trello and the TeamGantt extension based on the timeline. The colors correspond to the teams outlined above.

Primary Persona

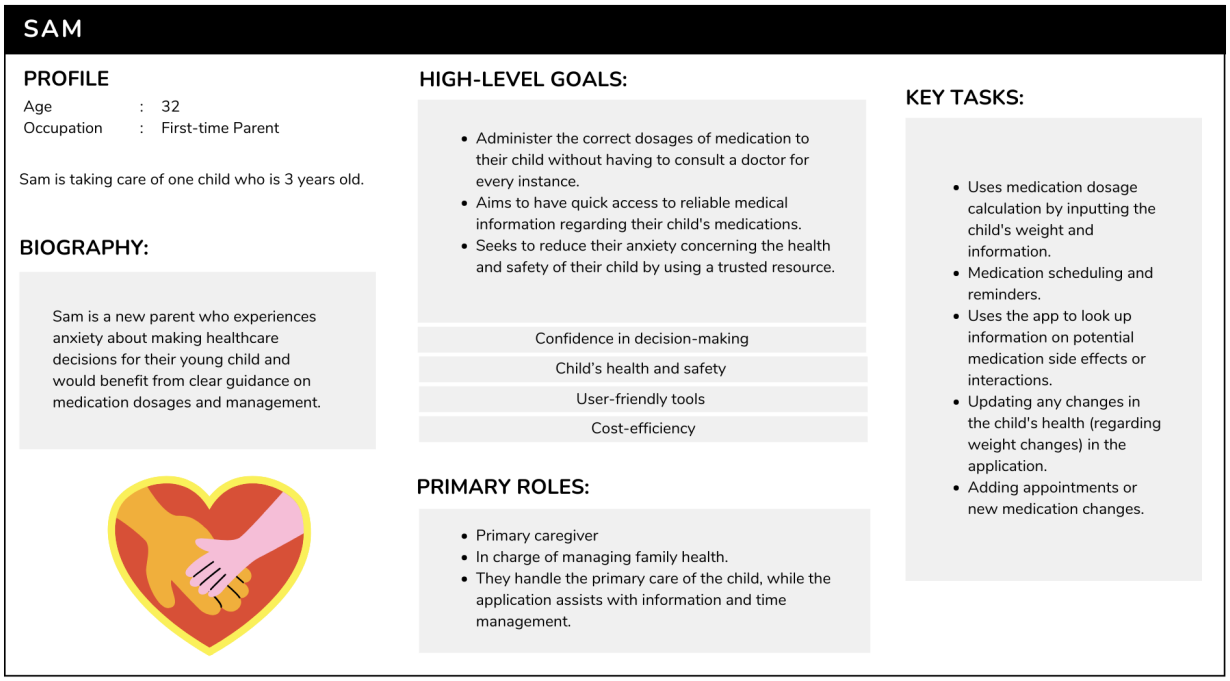

Figure 2. Primary Persona for our application, outlining their needs, primary roles, goals, and key tasks.

Resources

Center for Drug Evaluation and Research. (2016, August 17). *Identifying best practices for the safe use of pediatric cough and cold medications*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/safe-use-initiative/identifying-best-practices-safe-use-pediatric-cough-and-cold-medications

Center for Drug Evaluation and Research. (2020, May 15). *Pediatric information incorporated into human prescription drug and Biological products*. U.S. Food and Drug Administration. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pediatric-information-incorporated-human-prescription-drug-and-biological-products-labeling-good

Center for Drug Evaluation and Research. (2023, October 16). *Pediatric medical product safety*. U.S. Food and Drug Administration. https://www.fda.gov/science-research/pediatrics/pediatric-medical-product-safety

FDA Pediatric Dosage Guidelines for Over-the-Counter Medications. fda.gov. (2015, August). https://www.fda.gov/media/89475/download

Ghassab-Abdollahi, N., Nadrian, H., Shaseb, E., Kheirollahi, N., & Hashemiparast, M. (2024, April 19). *Self-administration medication errors at home and its predictors among illiterate and low-literate community-dwelling older adults with polypharmacy: A negative binomial hierarchical regression*. PloS one. https://pmc.ncbi.nlm.nih.gov/articles/PMC11029665

Weight-Based vs. Age-Based Pediatric Dosing: A Comparative Study. fda.gov. (2007, December 7). https://www.fda.gov/media/71586/download