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Design of a Precision Medication Dispenser: Preventing Overdose by Increasing Accuracy and Precision of Dosage

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ABSTRACT Liquid medication overdose in pediatric patients results in over 70 000 visits to the emergency room yearly in the USA. Various studies have demonstrated that the root cause of this high incidence is due to user and device error in dose measurement. The standard measuring cup and syringe suffer from the challenge of accurately measuring and dispensing viscous liquids, which comprise the majority of children's medication formulations. Here, we describe the development of a precision medication dispenser that overcomes challenges associated with viscous fluid flow at low volumes and flow rates, while incorporating various ergonomic and user-friendly features. The device performs with >95% accuracy and 94% precision across the 1–5-mL range of volume, a significant improvement when compared to current commercially available dispensers.

INDEX TERMS Liquid medication, dosage, administration error, viscous flow, overdose.

I. INTRODUCTION

THE pediatric population (<8 years of age) is especially sensitive to medication overdose, given the low body-weight range and systemic delivery of common medications. In fact, children are three times more susceptible to overdose and related complications than adults [1]. A report from the American Association of Poison Control Centres and the American Academy of Pediatrics demonstrated that in 238 cases of medication error for children 6 years and younger, incorrect dosing was the most common, and was most prevalent among children less than 1 year of age [2]. It noted that errors were very common when less than 1 mL of the medication was to be given and commonly resulted in hospitalization [3]. Furthermore, studies have reported narrow therapeutic windows for drugs such as acetominophen, where hepatotoxicity may result from a single acetaminophen dose of 120 to 150 mg/kg of body weight in children [4]. There exists a large volume of literature describing pediatric overdose and resulting negative sequelae due to acetaminophen [5], astemizole [6], xylometazoline [7], and ketamine [8]. Adverse effects include liver, heart failure, and sometimes death.

Most medications for this population are formulated as liquid suspensions or colloids, as they are easier to administer to infants than pills or capsules. Consequently, responsibility of accurately measuring the dose is shifted to the caretaker. The primary measuring devices used today are oral syringes and measuring cups, which have remained unchanged for decades and lack inherent functionality to ensure accurate, consistent dosing of viscous, liquid medication. Furthermore, both the syringe and measuring cup rely heavily on a user's handling for proper functionality [9].

Consequently, dosing errors lead to over 70,000 yearly pediatric overdose cases landing in the emergency department in the U.S. [3]. Furthermore, the reported rate of accidental medication poisoning has doubled from 36% to 64% since 2006 [10]. This high incidence with both over-the-counter (OTC) and prescription medications results from parents' difficulty in understanding non-uniform units (e.g. mg, mL, oz) and often insufficient unit labels on standard

IEEE Journal of Translational Engineering in Health and Medicine

dosing cups and syringes [11]–[13]. In fact, given the cheap manufacturing of plastic syringes and frequent washing during use, 75 % of marking on syringes are found to be inaccurate or missing [5]. With one in three patients in the US being health illiterate, interpreting and adhering to dosage schedules further compounds the issue [14], [15]. These challenges are exacerbated by user error, which can be an issue amongst sleep-deprived parents juggling numerous children on multiple medications. In a recent study published in *Pediatrics*, researchers asked parents to measure nine doses of liquid medication with different measuring units using a measuring cup or oral syringe [11]. 43% of the measured doses by cup and 16% by oral syringe were incorrect.

These statistics elucidate the frequency and source of liquid medication dispensing errors and highlight the clinical need for a device that enables reliable measurement of liquid medication volume, with decreased dependence on the user's proper execution of dosing. The primary barrier to the development of precise and accurate tools is the difficulty in handling viscous fluids in an easy-to-use and consistent manner. This work focuses on the generation and validation of a tool to accurately and directly dispense specific volumes of children's liquid medication, regardless of viscosity. This device reduces the onus of accurate measurement on the user by incorporating mechanisms to ensure greater accuracy and precision in the fluid measurement, thus eliminating measurement and dispensing as potential sources of error in liquid medication handling.

II. BACKGROUND AND APPROACH

We conducted a literature search and interviewed parents and clinicians to identify pain points in the medication dispensing process. Medication errors can be classified into four different categories based on error-origin: (1) prescribing, (2) transcribing, (3) dispensing and (4) administering. Dispensing errors are the predominant source of medication overdose in pediatric patient medication [1], [16]. Given the dependence of accurate dosing on proper fluid flow and device handling in both dispensing and administering, we chose to address these two steps in this work.

Common formulations of pediatric medication are highly viscous liquids for oral administration. Viscous fluids are challenging to dispense using standard dosing tools such as a measuring cup or oral syringe [17] predominantly because of their a) slow flow rates, yielding bubbles in syringes and b) adhesion to surfaces, yielding volume loss [18]. Current measuring tools are not designed for viscous fluid flow and therefore suffer from losses in volume and imprecise measurement. In bench-top tests, we measured between 1-5ml of Children's Motrin and Tylenol using a measuring cup and 5mL syringe (n = 25 trials, for each) and measured the volume dispensed into a weigh boat using a benchtop balance. We found a 30% loss in volume of medication due to viscous adhesion to surfaces using measuring cups and 5% using syringes.

In light of these problems, we designed a precision medication dispenser (PMD) targeted at improving dosing accuracy and precision to reduce medication errors in dispensing and administration. The dispenser presented is optimized for the handling of various viscous fluids, and fits onto standard medication bottles directly, replacing existing caps. The device enables a user to dispense medication and administer directly, to prevent fluid losses in an additional step. The use of such a tool will help prevent overdose by improving the accuracy of dose volume. Further, volume markings are etched into the device to prevent deterioration of printed markings after repeated use.

III. METHODS AND PROCEDURES

A. OVERVIEW OF THE PRECISION MEDICATION DISPENSER

We designed the PMD, a two-component cap, which attaches to the top of a standard medication bottle via the standard child-proof screw-thread mechanism. The first component is a mounted reservoir cap, featuring a large volume chamber that is designed to mitigate airlock during filling. The second component is a detachable spoon-like dispenser, which tunes dosage volume and is used to directly administer medication (Fig. 1). The PMD operates between 1- 5 ml, typical dosing volumes for children.

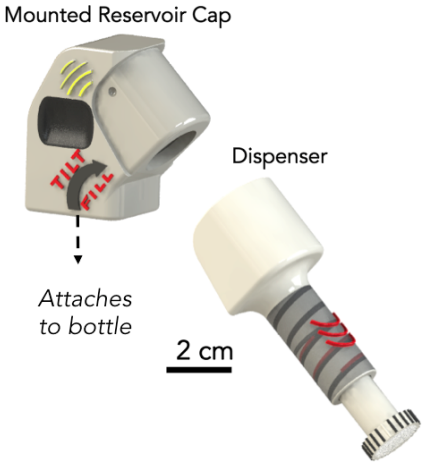

FIGURE 1. Schematic of PMD, consisting of the mounted reservoir cap and a detachable spoon-like dispenser.

B. OPERATION AND MECHANISM OF THE PRECISION MEDICATION DISPENSER

First, to set a desired volume, the user twists the volume adjuster screw on the detachable dispenser. Each 180 degree turn in the counterclockwise direction increases the volume 0.5 ml. Second, to fill the dispenser with liquid medication, the user simply tilts the device to fill the cap's reservoir. Upon reversion, fluid flows into the detachable spoon and levels off at the set volume, with excess flowing directly back into the bottle. Finally, the user detaches the dispenser from the cap and uses the rounded, spoon-like interface to administer the

medication to the patient (Fig. 2). Notably, no volume adjustment is required for subsequent administrations, relieving a human component from the dosing process.

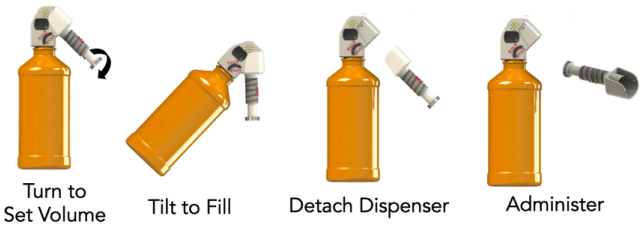

FIGURE 2. **Process of dispensing and administering liquid medication using the precision medication dispenser.**

1) FLUID FLOW

The key challenge in designing an accurate measurement and dispensing system was ensuring adequate flow of viscous liquids. This was especially challenging in a closed system, where the lack of air return prevents gravity-driven fluid flow. Therefore, we analyzed the nature of fluid flow from standard bottles and orifices to identify the constraints and design around them.

Small orifices are easily occluded by viscous fluid during dispensing due to a block of airflow. Moreover, as long as surface tension forces at the fluid-air interface are not overcome, gravitational pressure alone is the driving force of fluid out of a bottle. We model this flow as laminar Pouseille flow through the outlet nozzle driven by hydrostatic pressure of the fluid contained within the bottle:

$$\rho g H = \frac{8\mu L Q}{\pi r^4}$$

where ρ is the density of the fluid (1 kg/m^3), g is the gravitational constant (9.8m/s^2), H is the height of the liquid in the bottle when inverted, μ is the viscosity of the liquid (1.9 cP for water) L is the length of the nozzle (0.5cm), Q is the flow rate out of the nozzle, and r is the diameter of the nozzle.

With a nozzle diameter of 1cm, this nozzle allows a maximum flow rate of 0.031ml/s. However, if an air return path is present, this generates an additional driving force of fluid out of the bottle, due to atmospheric pressure as well as buoyancy of the lighter air. We incorporate this into our model by adding atmospheric pressure to the driving force (P_{atm}). Theoretically, this increases the flow rate through a 1cm nozzle to 2618 ml/s. While this result inherently circular flow profile assumed in Pouseille flow, it nevertheless serves as an 'order of magnitude' calculation of expected flow rates.

The PMD uses a spacious reservoir to overcome the problem of low flow rates due to air return. We maintained a large outlet nozzle size and ensured adequate supply of air within the cap to yield return. Figure 3 shows a cross section of the PMD and the expected air and fluid flow paths. Empirical tests (n = 35) with 7 different users showed flow rates between 0.5ml/s and 1.7ml/s under normal usage conditions across 3 different viscosities (1cP, 450cP, 1010cP). The creation of the reservoir and maximization of outlet nozzle size in the PMD effectively increased fluid flow rates and prevented air lock.

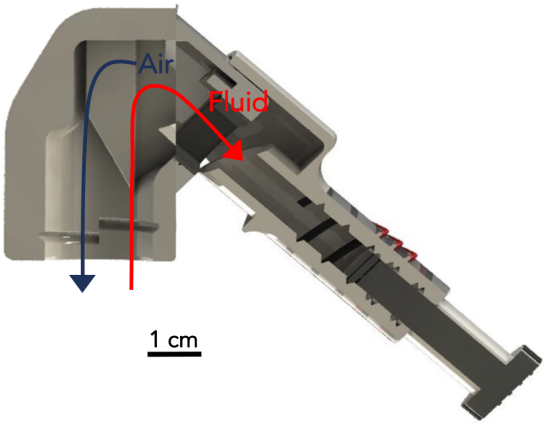

FIGURE 3. **Cross-section of the cap design illustrating divided fluid-air flow pathways achieved with the large reservoir.**

2) SEAL AT CAP-DISPENSER INTERFACE

Leakage is a significant concern when handling fluids in multi-component devices. This is especially true for viscous fluids, which become sticky and difficult to clean once dry. The final cap design seals a single circular interface between the dispenser and cap to reduce the occurrence of leaks. To achieve the right seal tightness to prevent leaks but ease removal of the dispenser, we incorporated a rubber seal on the mounted interface (Fig. 4A). In designing this interface we modeled the seal as a simple thin-walled tube undergoing a predetermined strain. Figure 4B shows this model, along with a small differential element analysis to determine the frictional force, F, at this boundary. From this, we can directly calculate the frictional force, f, required to overcome this stress and remove the dispenser from the cap. For a rubber-plastic interface, we have a coefficient of friction, $\mu = 0.8$, and an elastic modulus, E = 2.5MPa. We design the dimensions of the interface (H, D) such that the seal undergoes a 15%-25% strain once the spoon is inserted. Under this strain, there is sufficient compression of the rubber to prevent fluid from leaking past it. Further, the resulting force required to detach the dispensing unit from the cap was designed to be 13-19N, which is well within the bounds of force normally exerted to open bottle caps [19]. Overall, this design ensures a tight seal in the device without compromising the ease of detaching the components.

3) STABILITY OF THE BOTTLE-CAP SYSTEM

A key concern in the PMD design, whereby a cap is mounted directly onto the bottle, was the addition of top-heavy components to a plastic bottle, rendering the system potentially unstable. As the bottle becomes emptier, the propensity to tip over increases, which would potentially lead to a spill if the dispenser was detached from the cap. We performed a

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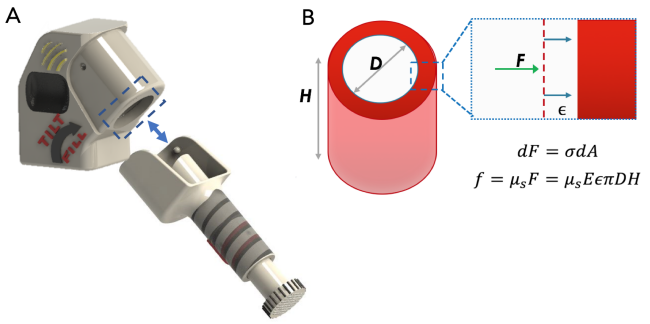

FIGURE 4. **The mounted interface features a rubber seal with optimized dimensions to prevent leaking and enable easy removal of the dispensing spoon.**

weighted center of mass analysis across the range of volumes in a bottle (full to empty) and determined the critical angle at which the bottle would tip over. This was done using the standard weighted center of mass equation:

$$x_{CM} = \frac{1}{\mathrm{M}} \sum_{i=1}^{n} m_i x_i$$

where m is the mass of each component, x is the respective coordinate from a reference origin, and M is the total mass of the system. To maximize the tipping angle, while accounting for the other constraints of the design, we symmetrically weighted the mass of the PMD around the central axis of the bottle wherever possible. The resultant tipping angle is 23 degrees when the bottle is full, and reduces to 14 degrees when the bottle is empty. We believe the stability can be further enhanced with the use of lighter materials.

4) DISPENSER'S SCREW-BARREL DESIGN

The screw-barrel design took into consideration factors of balance, ease of use, resolution of volume measurement, sealing, and forces required to turn the screw. Every half turn of the screw is equivalent to 0.5 ml of volume change. We chose this volume:length ratio to balance the accuracy of the device with its propensity for tipping. Decreasing the radius of the screw barrel yields a device with greater resolution since a greater turn of the screw will be required per unit volume. However, decreasing the diameter of the screw barrel proportionally increases the length of the screw. Consequently, the device's dimensions would have increased, and the center of mass moved away from the bottle's center of mass, increasing the likelihood of tipping. We therefore balanced these two factors to decide on a radius that required a 360° turn for each milliliter, a convenient dimension from the user perspective as well.

The barrel part of the dispenser consists of five complete female-type threads. To reduce friction and thus the force required to turn the screw, only 2 complete male-type threads are present on the screw (Fig. 5A). The starting location of these threads is fixed such that screws are engaged for complete range of volume (1-5 ml) (Fig. 5B). This also mitigates fluid leakage. An O-ring placed at the end of the screw part acts as the first level of seal. However, the O-ring alone is insufficient to seal the gap created between female threads in barrel and root of the screw. Since the male type threads are always engaged after the O-ring, an intact seal is generated by combining an O-ring with strategically placed male-female threads.

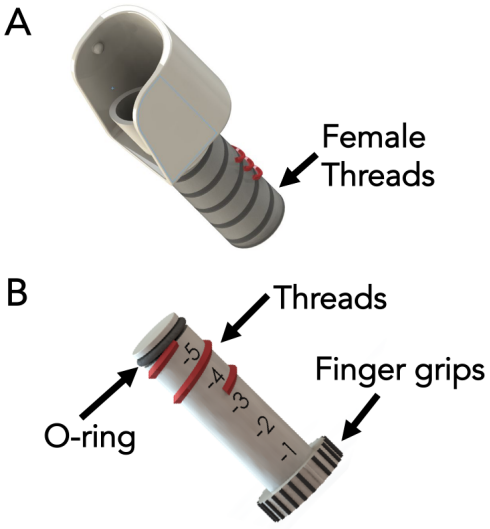

FIGURE 5. **Cap designs showing threads and sealing in dispenser assembly.**

5) ERGONOMIC FEATURES

Given the target use case of the PMD, we incorporated a number of features to optimize ergonomics and safety. These are outlined below and illustrated in Figures 5 and 6.

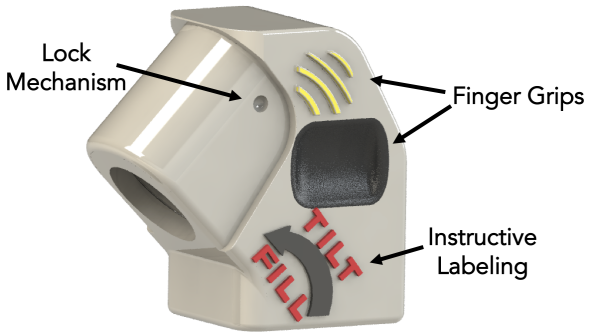

FIGURE 6. **Ergonomic features of the cap include finger grips, a locking mechanism for the dispenser, and instructive labeling.**

Rounded Spoon to Minimize Fluid Loss: The edge of the dispenser is rounded and spoon-shaped to allow the user to directly administer medication into the mouth. Moreover, the rounded edge prevents fluid adhesion when compared to similarly structured sharp or linear edges.

Clear Material Enables Visualization of Fluid Flow and Visual Confirmation of Dose: The PMD is created with clear plastic, enabling the user to visualize the flow of fluid and confirm the level of fluid in the dispenser. If the bottle is

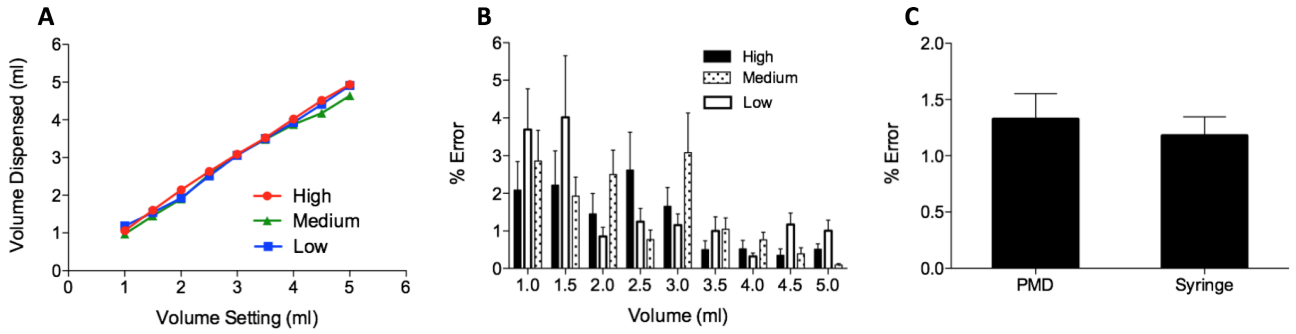

FIGURE 7. Bench top testing illustrating the (A) accuracy and (B) precision of the PMD in dispensing liquids of varying viscosity (low, $\mu = 1$cP; medium, $\mu = 450$cP; high, $\mu = 1010$cP) in 0.5ml increments from 1ml to 5ml. (C) PMD precision compared to standard oral syringe supplied with pediatric liquid medication.

empty or the cap is not properly functioning, the user can easily detect that the detachable spoon is not entirely filled. The ability to visually confirm the dose adds a level of safety.

Integrated Measuring and Administration Components Prevents Loss/Separation of Device From Medication: Syringes and measuring cups are commonly lost since they are not required to close the medication bottle. The design of our PMD inherently prevents the user from losing device parts that are essential to the measurement of dose. The PMD screws directly on the bottle and requires the dispensing spoon to be re-attached after use to close the system.

The Cap Is Sized to Fit Into the Average Palm, and incorporates finger and handle grips as well as instructive labeling.

Child Proof Safety Mechanisms: A threading is incorporated into the reservoir cap to add a layer of safety to prevent accidental opening by children. A notched lock is also provided in the dispenser-cap interface to for this end.

6) PROTOTYPING

Design of the PMD was performed in SolidworksTM. Prototypes were 3D printed using a Stratasys Connex 3 Objet500 with VeroClear material and silicone elastomer for the seal.

IV. TESTING AND RESULTS

A. ACCURACY AND PRECISION

The accuracy of the device at each dispensing volume from 1ml to 5ml in increments of 0.5ml was tested. This test was performed with liquids spanning the range of viscosities commonly found in medication: 1cP (deionized water), 450 cP, and 1010cP (Children's Motrin®). Each solution was dispensed into a beaker using the PMD and placed on a bench top balance to measure the actual volume dispensed. For comparison, liquid medication was also dispensed with a standard oral syringe supplied with the oral medication. As seen in Fig. 7, the device is accurate (within 5% of desired volume) in dispensing from 1ml to 5ml for all 3 solutions.

Significantly, the volume dosed by the cap is consistent, with $<5\%$ error at all volumes, and $<1\%$ error for volumes 3.5ml and above. We compared this performance to that of the oral syringe and found that the PMD performed with 1.33% error across all volumes, compared with 1.18% with oral syringe (Fig. 7C). This shows our device performs with the same precision as an oral syringe and without the need to re-draw liquid with each dispense. The volumes delivered by the PMD have been calibrated to account for any losses due to surface adhesion of fluid to the material.

B. LEAKING AND SEALING

We conducted a user study to examine the extent of spillage in normal use. In a study of 25 people using the device to dispense 5 mL of fluid – making the cap most prone to spillage – there was only 1 instance in which a minor spill occurred. This suggests that the cap was designed with sufficient ergonomic insight and mechanical sealing to avoid liquid spills and leaks, respectively. Since some medications also require shaking before use, we performed a trial ($n = 50$) in which we shook a half-full bottle of medication with our cap affixed and assessed leakage, especially near the dispenser/cap interface and cap/bottle interface. No leaks were detected across all trials.

C. AIRLOCK

In a separate trial ($n = 35$), a syringe and the PMD were used to measure volumes of water and liquid Motrin®medication ranging between 4-5mL. In this volume range, the cap is most prone to problems associated with airlock and bubbles. When measuring water, bubbles were identified in 6 cases in the syringe and zero cases in the PMD. Using liquid Motrin®, there were 14 cases of airlock in the traditional syringe, and 3 in the PMD. Additionally, in 11 trials, the syringe failed to measure volumes within a tolerance of 25% of the intended volume due to airlock at the interface of the medication and the plastic tip. This experiment demonstrated the efficacy of the reservoir-based design in preventing airlock.

D. CLEANING

The device can be easily cleaned using soap and water to prevent contamination of the medication. In benchtop tests,

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numerous users washed the devices under running water and left them out to dry. We observed no residues or crystallization of compounds at any interface or surface.

Overall, the design of the PMD effectively improves the accuracy and precision of liquid volume measurement and dispensing by accounting for viscous fluid flow properties and other user-error tendencies.

V. CONCLUSION

Pediatric liquid medication overdose is a prevalent problem with severe and potentially fatal consequences. Measuring caps and oral syringes are associated with significant user error, and yet have remained unchanged for decades. These common tools are often erroneous due to design limitations associated with viscous fluid flow and a high dependence on user reliability.

We developed a novel precision medication dispenser which serves a range of viscosities through a process of fluid mechanical analysis and user-centered design. The design is simple and intuitive, and achieves significantly more accurate and consistent dosing using fixed volume dispensing. With our design, a user can confidently dose multiple times without repeatedly measuring a predetermined amount of volume at every dispense, or dealing with confusing and conflicting units of volume or concentration. The device performed with $>95\%$ accuracy and $>94\%$ precision across a range of volumes. This cap is a significant step to addressing the important issue of liquid medication overdose in children.

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