# Device to Limit Swallowing Volume for Swallowing Therapy and Evaluation

**Preliminary Design Report**

**University of Wisconsin-Madison**

**Department of Biomedical Engineering**

**BME Design**

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## *Design Problem Statement:*

To design a cup and/or a bottle that restricts the amount of liquid that is given to a patient. Ideally we would be able to "set" the cup and/or bottle to dispense a specific volume that is deemed as an appropriate bolus size for the patient. Ages of patients will range from birth to approximately 10 years, but the user of the device may be an adult (*i.e.,* adults may operate device when feeding infants). The goal of this project is to create a therapeutic device that can be used to treat certain swallowing disorders (*e.g.,* aspiration).

## *Swallowing Biomechanics:*

Swallowing is a relatively complex activity that requires neuromuscular coordination. Motor units from the brainstem are connected to muscles of the mouth, pharynx, larynx, and esophagus. Action potentials propagating from the brainstem signal the initiation of individual swallows.

A swallow consists of four phases: oral preparatory, oral propulsive, pharyngeal, and esophageal. Edible materials are broken down and dissolved by several enzymes located in the mouth. This process is known as the oral preparatory phase. The oral propulsive phase refers to the propelling of food from the oral cavity into the oropharynx. When liquids are being swallowed, the pharyngeal phase follows immediately after the oral propulsive phase. During the pharyngeal phase, the tongue pushes backward and downward into the pharynx to propel the bolus down. The esophageal phase propels the bolus downward even further by a peristaltic wave. The lower esophageal sphincter relaxes and allows the bolus to enter the stomach. This sphincter then closes, preventing gastroesophageal reflux from the stomach (Palmer *et al.*, 2000).

### *Swallowing Disorders in General:*

Impaired swallowing, or dysphagia, can cause severe damage to the health of an individual. There are numerous factors that may influence one's susceptibility in developing swallowing disorders. These include neurological disorders such as Parkinson's disease, multiple sclerosis, and stroke. Other causes may include structural lesions, psychiatric disorders, connective tissue diseases, surgical resections, and radiation fibrosis. Symptoms of dysphagia may include coughing or choking with swallowing, food sticking in the throat, drooling, recurrent pneumonia, nasal regurgitation, and aspiration (Palmer *et al.*, 2000).

### *Swallowing Disorders and Aspiration:*

Aspiration is the passage of food or liquid through the vocal cords and into the trachea. Excessive aspiration is one of the most prevalent symptoms of swallowing impairment. Frequent aspiration may lead to the development of serious respiratory complications, such as airway obstruction and aspiration pneumonia (Palmer *et al.*, 2000).

The extents to which aspiration problems develop are influenced by several factors. Aspirating relatively large quantities is much more hazardous than aspirating small amounts of liquid (Joanne Robbins, pers. comm.). Aspirating material deep inside the distal airways is much more hazardous than aspirating material into the trachea. The chemical properties of the aspirate may also affect the severity of tissue damage. Aspirating refluxed stomach contents with a low pH (*i.e.,* large hydrogen ion concentration) may cause serious damage to the pulmonary parenchyma. Bacterial pneumonitis may occur when infectious materials are aspirated (Palmer *et al.,* 2000).

## *Goals of the Design Project:*

Reducing or eliminating the prevalence of aspiration is one of the primary goals of our device. Laurie Matzdorf, our client, is a senior clinical speech pathologist at the University of Wisconsin Hospital. She is involved with diagnosing, treating, and rehabilitating relatively young children with dysphagia. She believes a device with the capability of regulating small volumes of liquid given to her patients will substantially reduce the amount of aspiration.

## *Design Specifications:*

Our device must be able to accurately dispense small volumes of liquids in a container that is designed as a cup and/or a bottle. The patient should be able to adjust the amount of liquids that are dispensed ranging from 1ml to 5ml (in 1ml increments). All detachable components should be large enough so that they cannot be swallowed by young children. We must incorporate materials that are chemically inert, non-dissolvable, and capable of being approved by the FDA for clinical use. Ideally, our device would also be dishwasher-safe and microwaveable. Total costs of the materials need to be minimized, possibly under $13.00. The device needs to be able to hold a total volume of approximately 250ml. Ergonomics and aesthetics are also important considerations.

Generally, the device will be used by children with ages ranging from newborn to 10 years old. Adults may need to operate device when children are too young to do it themselves.

A comprehensive list of product design specifications (PDS) is described in Appendix A.

## ***Currently Existing Devices:***

There are a few devices that currently are available to the public that can perform tasks similar to what our client is asking for. However, we believe that it is possible to design a device that specifically satisfies the design requirements and can be produced at a relatively low cost. Such a device does not currently exist.

A United States Patent search revealed that there is already a patent claiming rights to a mug with an insert for dispensing measured quantities of liquid (U.S. Patent #4921112; USPTO, 2001). The main object of this invention is to facilitate the feeding of drinking liquids to elderly patients who have difficulty in drinking from ordinary drinking glasses. Often these patients cannot control the proper drinking and swallowing of liquids, resulting in too much liquid in the patient's mouth and sometimes spilling or drooling. When the mug is tilted, a proper dosage of drinking liquid will automatically enter into the dosing chamber, whereupon the dosage can easily be drunk by the patient without any risk of receiving too much drinking liquid into the mouth. In principle, young or healthy persons who have difficulties in swallowing properly can also use these mugs.

This device satisfies most of the specifications of our client, but the amount of liquid that is dispensed cannot be adjusted in 1ml increments, which is one of our main design specifications.

Pubs (*i.e.,* bars) have screw attachments on liquor bottles that have the ability to regulate the amount of alcohol that is dispensed into a shot glass. While it is generally not a device used to treat swallowing disorders, perhaps the mechanical components of this relatively simple device can be incorporated into our design.

Burets are often used in biology and chemistry labs for acid-base titrations and dispensing regulated volumes of liquid reagents. It would be possible to design a device that contains one or more stopcocks that can be manually operated by a patient. This would enable users to measure and dispense very accurate volumes of liquids.

## ***Proposed Design Alternatives for a Bottle:***

*1) Variable Head*:

The Variable Head model is a fairly simple design. It consists of a bottle with an open bottom (see Figure 1.1 a), and nipple cap (see Figure 1.1 b). The “head” or “bottom” of the bottle is the part of the bottle that is in contact with a surface when the bottle is standing upright on a surface. On the Variable Head model there would be different “heads” to put on the end (see figure 1.1 c). The head would form a watertight seal so that no liquid would escape from the bottle. When the bottle is tipped into the feeding position with the nipple cap facing downward, the “head” would be pulled down the bottle by gravity. Being pulled down would cause liquid to be forced from the bottle.

The rate at which the liquid would be forced from the bottle would be adjusted by putting on a different "head" (see figure 1.2). The different heads would have different masses and thickness, which would cause them to be pulled down by gravity at different rates, thereby changing the rate at which liquid is dispensed.

*2) Moveable Head with Clicker:*

The Moveable Head with Clicker starts off much like the Variable Head design. It consists of a bottle with open bottom (see figure 2.1 a) and nipple cap (see figure 2.1 b). Again the "head" or "bottom" of the bottle is moveable and controls the volume of liquid dispensed (see figure 2.1 c). In the Moveable Head with Clicker model the bottle has tracks on the inside of the bottle directly across from each other (*i.e.* where the distance between the tracks equals the diameter of the bottle) (see figure 2.1 g). The groves in the tracks are separated by the length corresponding to the volume of 1cc apart from each other (*i.e.* the length, L, between the groves would be $(\pi^2)$ RL=1cc so L=1cc/($(\pi^2)$ R) where R is the radius of the bottle). The "head" fits into these tracks. A spring-loaded lever on the top of the head controls the head (see figure 2.1 e). The lever is easily pulled by someone's thumb or index finger and is forced back into its original position by a spring (an idea we developed from the eppendorf-micopipet). A knob is on top of the lever with numbers 1,2,3,4, and 5 corresponding to the desired volume to be delivered with each pull of the lever (see figure 2.1 f). For example, if the knob is set to 5, corresponding to 5cc, when the lever is pulled down the "head" will be forced down 5 groves in the bottle, dispensing 5cc of liquid out of the bottle. The nipple cap would have to have some sort of one-way valve so an infant could not use negative pressure to receive liquid (*i.e.* the only way the infant could receive liquid would be through a pull of the lever).

*3) The Dam idea:*

The Dam idea starts off with a regular bottle (see figure 3.1 a). The cap in the Dam Idea is modified and it controls the volume of liquid dispensed. The cap screws into the bottle and ends in a nipple like most other caps (see figure 3.1 b), but the cap in the Dam Idea is longer than most regular caps. Inside the cap, a few centimeters down from the end of the bottle is the first of two “blocks” (see figure 3.1 c). This block will be a thin plastic sheet in the shape of the cap. In resting position (see figure 3.1) this “block” will not be blocking the entire cap so liquid can pass it by. When the liquid passes by the first block it will continue until it reaches the second block (see figure 3.1 d). The second block is closer to the end of the cap and completely seals off the end of the cap in resting position. The liquid will therefore completely fill up the volume between the two blocks in resting position (see figure 3.1 g). Both blocks are connected to a lever that sticks out from the cap (see figure 3.1 e). In resting position this lever is angled toward the end of the cap, or away from the bottle. When the lever is pulled up by the operator the following events happen sequentially (see figure 3.2):

1) The first block completely closes so no addition liquid can get by.

2) The second block opens up and the liquid is pulled by gravity into the actual nipple part of the cap where it can be sucked out by the infant.

When the lever is pushed back into its resting position the same two events happen in opposite order so the infant can obtain no additional liquid. A knob on the cap connected to the second block (d) is numbered 1,2,3,4, and 5, corresponding to 1-5cc (see figure 3.1 f). The knob will move the second block to a distance from the first block corresponding to the desired volume to be dispensed. The length, L, between the two blocks when the desired volume is 1cc will equal $L=1cc/((\pi^2) R)$ where R is the radius of the cap between the two blocks.

*4) Syringe Connection:*

The Syringe Connection begins with a regular bottle (see figure 4.1 a). The cap of the bottle screws into the bottle but is highly modified from the normal nipple cap. The cap begins with a tube running from the bottom of the bottle to the bottom of the syringe with nipple cap (see figure 4.1 b). Where the tube meets the syringe with nipple cap there is a block connected to a lever (see figure 4.1 c), which in resting position does not allow any liquid into the syringe. The block can be made of a variety of materials, but would probably be made of plastic. When the operator wishes to fill the syringe with liquid from the bottle, he/she will push the lever into the open position where liquid can enter the syringe. The operator will then pull the syringe up (see figure 4.1 d), pulling liquid into the syringe. When the desired amount of liquid is pulled into the syringe the lever is pushed back into resting position so no liquid can flow back into the tube or bottle. To force the liquid out of the syringe the operator must pull a second lever that is connected to the middle of the syringe (see figure 4.1 e). The lever will force the syringe down to dispense the desired volume of liquid out of the nipple end. There will be a knob labeled 1,2,3,4, and 5 corresponding to 1-5cc (see figure 4.1 f). The knob at the end of the lever and will restrict the distance the lever can be pulled down. If the operator only wants to deliver 1cc the knob will be adjusted to 1 and the lever will stop after being pulled a distance corresponding to the 1cc volume. There will be a safety on the syringe that will not allow the actual syringe to be pushed down on its own to stop any accidents of unintentionally pushing the syringe down (*i.e.* the only way to get liquid out of the syringe is to push on the lever e).

*5) Modified Buret:*

The Modified Burette idea combines a chemistry buret with a bottle. The bottle will be made of some smooth material on which clear graduate markings can be made. Markings will be made every 1cc on the bottle. The length, L, between the marks will equal L=1cc/(π^2R) where R is the radius of the bottle. The cap will be a normal nipple cap which screws into the bottle. Approximately 4 to 5cm above the cap in the bottle there will be a stopcock that will be used to dispense the liquid into the cap. The amount of liquid dispense will simply be adjusted by how long the stopcock is opened. The operator will have to use his/her sight to determine how much liquid looking at the graduate markings.

*6) Mouse Bottle:*

The Mouse Bottle is very similar to the type of bottle small from which pet rodents drink. The bottle would be similar to a normal bottle with the exception that it wouldn't narrow toward the end (*i.e.* the radius would remain constant throughout the entire bottle) (see figure 6.1 a). The cap of the Mouse Bottle would screw on but would not come to a nipple like all the other caps. Instead, the cap would consist of a small tube (see figure 6.1 b) with a small ball at the end of the tube that would block the end of the tube (see figure 6.1 c). The ball will be held in the tube by the end lip (see figure 6.1 d) of the tube where the radius of the tube is smaller than the ball. When the infant wants to receive liquid it will simply push the ball back with its tongue and let a small amount of liquid in. It would be hard to adjust the amount of liquid received by the infant using this apparatus.

## ***Proposed Design Alternatives for a Cup:***

*1) Cup with Eppendorf Repeater Pipetter:*

Eppendorf Repeater Pipetters are often used in laboratory research (Fischer, 2001). They enable scientists to dispense small amounts of liquid relatively rapidly (compared to traditional micropipets that have to constantly be refilled after each dispensing event). It would be possible to design a cup that has one of these pipetters directly attached to the inside of a cup by a series of bolts or screws. The syringe can be filled to about 5ml using lever 2 (Figure 7). The rotating knob allows the user to select different volumes (*i.e.,* set to appropriate bolus size). Lever 1 will dispense the specified amount of liquid when it is depressed (Figure 7). This liquid is injected into the bottom of the cup and becomes available to the user for drinking. Patients can operate this device as a normal cup; all they need to do is depress the spring-loaded lever 1 for each sip. We would also need to develop a method for detaching the pipetting mechanism to refill the syringe.

*2) Cup with Modified Repeater Pipetter:*

This device is a cup with a liquid reservoir fitted with a dispensing mechanism similar to the Eppendorf Repeater Pipetter (Figure 8). The reservoir can be filled to the top with almost enough liquid to fill the entire volume of the cup. A syringe-like disk is fitted to the inside of the reservoir and can be pushed downward to dispense the liquid through a nozzle at the bottom of the cup. A lever is positioned conveniently near the handle by the thumb placement. This increased ergonomic consideration may make dispensing the liquid relatively easy for the patient. Mechanisms need to be implemented in the reservoir to mechanically push the syringe down. A knob fitted on the top of the reservoir may adjust the volume of dispensed liquid. The bottom of the cup can have a slanted angle that directs liquid to one side of the cup. A straw can be inserted to that side of the cup and liquid is then available to the user. Or, if we don't use a straw, the reservoir would need to be molded in a way so that patients may comfortably access the liquid.

*3) Gravity Dispenser:*

Perhaps we could design a cup that utilizes gravitational forces to dispense a specified volume of liquid when the device is moved in a certain position. There are several devices currently on the market that are generally used as toys for young children that utilize liquid flow and gravitational forces (*i.e.*, pendulum-swinging birds that can teeter for long periods of time without the aid of external physical forces). In our proposed design, the cup would dispense a certain amount of liquid when it is rotated into an upright position. The user would lift and rotate the cup upside-down, allowing the small volume to be drunk. When the cup was rotated back to the upright position, the cup would refill. One possible drawback for this device is that it would have to be rotated for each sip.

*4) Reagent Dispenser*

Several chemistry and biology laboratories have dispensing devices that screw into the tops of bottles containing liquid reagents. Our device could implement similar mechanical operations to adjust the amount of liquid that is given to a patient. Figure 9 displays a schematic drawing of how this could be incorporated into a cup with a compartment for the specified bolus size. This design would have a relatively large reservoir to hold most of the fluid (≈ 250ml). The patient could adjust the amount of fluid that is dispensed by setting the cylinder to different volumes. Upon lifting and letting go, the appropriate bolus size would dispense into the small liquid reservoir. The patient would then lift the cup to the mouth, where he or she may drink the fluid that was dispensed.

## *Evaluation of Bottle Design Alternatives:*

Table 1. Evaluation matrix for 6 proposed bottle design alternatives to regulate the amount of liquid that is given to an infant. Design specifications are listed in order of priority, with 12 being the most important. Ratings of each design at each specification are 3 = good, 2 = fair, and 1 = bad.

| **Prioritized Design Specifications** | **Variable Head** | **V.H. with Clicker** | **Dam Idea** | **Syringe Connection** | **Modified Buret** | **Mouse Bottle** |
|---|---|---|---|---|---|---|
| **(12) Accuracy** | 2 | 3 | 3 | 2 | 2 | 1 |
| **(11) Adjustable Bolus Size** | 3 | 1 | 3 | 2 | 2 | 1 |
| **(10) Pieces can't be Swallowed** | 2 | 3 | 3 | 1 | 3 | 3 |
| **(9) FDA Approvable** | 2 | 3 | 3 | 2 | 3 | 2 |
| **(8) Longevity** | 2 | 2 | 2 | 2 | 2 | 2 |
| **(7) Cost** | 1 | 1 | 2 | 2 | 1 | 2 |
| **(6) Size and Weight** | 2 | 2 | 2 | 2 | 2 | 1 |
| **(5) 250 ml Reservoir** | 3 | 3 | 2 | 3 | 3 | 2 |
| **(4) Ergonomics** | 2 | 2 | 2 | 1 | 3 | 1 |
| **(3) Dishwasher Safe** | 2 | 2 | 2 | 1 | 1 | 2 |
| **(2) Microwaveable** | 2 | 2 | 1 | 2 | 3 | 1 |
| **(1) Aesthetics** | 2 | 2 | 3 | 1 | 2 | 1 |
| **Totals** | 165 | 174 | **197** | 143 | 176 | 130 |

## ***Proposed Solution for Bottle:***

We believe that the bottle with the dam mechanism is the best idea for solving our design project. Analysis of the evaluation matrix suggests that the dam idea meets the required specifications more than any of our other design alternatives for the bottle (Table 1).

The "dam" mechanism implemented in this design has the potential to be very effective in delivering a regulated amount of liquid to an infant with dysphagia. It will use a relatively simple mechanical lever system to isolate small volumes of liquid and make them available to the patient by clicking one simple lever. These volumes will be adjustable to meet the patient's needs, and accurate so as to deliver the correct amount of liquid. All of the materials will be chemically inert, non-dissolvable, and approvable by the FDA as a safe product for clinical use. We will attempt to maximize shelf life and durability by researching the strengths of different materials. Cost of the final prototype will be carefully monitored and minimized by the end of the semester. Ergonomics and aesthetics will be thoroughly developed to maximize user comfort.

Of all the design alternatives we brainstormed, the dam idea stood out as being the best way to meet our client's needs.

### *Evaluation of Cup Design Alternatives:*

Table 2. Evaluation matrix for 4 proposed cup design alternatives to regulate the amount of liquid that is given to a patient with dysphagia. Design specifications are listed in order of priority, with 12 being the most important. Ratings of each design at each specification are 3 = good, 2 = fair, and 1 = bad.

| **Prioritized Design Specifications** | **Cup with Eppendorf Repeater Pipetter** | **Modified Cup with Pipetter** | **Gravity Dispenser** | **Reagent Dispenser** |
|---|---|---|---|---|
| **(12) Accuracy** | 3 | 3 | 1 | 3 |
| **(11) Adjustable Bolus Size** | 3 | 3 | 2 | 3 |
| **(10) Pieces can't be Swallowed** | 3 | 3 | 3 | 2 |
| **(9) FDA Approvable** | 3 | 3 | 3 | 3 |
| **(8) Longevity** | 2 | 3 | 2 | 3 |
| **(7) Cost** | 1 | 2 | 2 | 3 |
| **(6) Size and Weight** | 2 | 3 | 2 | 1 |
| **(5) 250 ml Reservoir** | 1 | 3 | 2 | 3 |
| **(4) Ergonomics** | 1 | 3 | 3 | 1 |
| **(3) Dishwasher Safe** | 2 | 2 | 3 | 2 |
| **(2) Microwaveable** | 1 | 1 | 2 | 2 |
| **(1) Aesthetics** | 1 | 3 | 2 | 1 |
| **Totals** | 179 | **220** | 170 | 197 |

## ***Proposed Solution for Cup:***

We decided that a cup with a relatively large reservoir capable of dispensing small volumes of liquid in 1-5ml increments would be the ideal cup design solution for our client. The evaluation matrix on Table 2 suggests that this device would satisfy most of the design specifications very well.

A cup with a liquid reservoir containing a mechanical dispensing mechanism thoroughly meets the demands of our client. This device will be able to dispense accurate volumes of liquid in increments of 1ml from a range of 1-5ml (*i.e.,* it is adjustable). It will be made of non-swallowable objects, FDA approvable, and have a relatively long shelf life. The cost to research and develop the mechanical components may become expensive, but we will constantly monitor the cost of materials to make sure the final prototype can be made rather cheaply. This device will be very comfortable, even fun for the patient to use. We will carefully consider the ergonomics of our design and make it very easy to use. This design has the potential to be dishwasher safe, and easy to clean by hand if necessary. Appearance of the design will also be carefully considered.

## ***Potential Problems and How They Will be Addressed:***

The last half of the semester will be devoted to researching and developing the prototype design to best suit our client's needs. As a team we will have to decide what are the best approaches to take with our project and work together to accomplish our goal of developing a working design. To do this we will have to communicate effectively, listen to each other's ideas, and spend time in the lab putting things together.

Like any design project, there are several potential problems that may arise which will need to be addressed and overcome. With the dam idea, we will have to figure out how exactly we should put the mechanical components of the lever system together and how we will adjust the bolus size. Several tests will need to be conducted to try to reduce the amount of excess liquid build-up in case the patient does not swallow all of the liquid that is dispensed each time. We feel that this will not be overwhelmingly difficult, but will require several hours of lab work to develop an effective method.

The cup with the modified pipetter is a very interesting and creative idea, but putting it together may require extensive time to develop. We visited a lab at the UW-Hospital to research the internal mechanical components of the Eppendorf Repeater pipetter. We found that the mechanics of this device were relatively simple and would be feasible to make ourselves. Further research of this device may enable us to develop a similar mechanism and implement it in our proposed cup idea.

# References

Fischer Scientific Online Catalogue
https://www2.fishersci.com/main.jsp (16 September 2001).

Palmer, J.B., Drennan, J.C., and Baba, M. 2000. Evaluation and treatment of swallowing impairments. *American Family Physician* 61: 2453-62.

United States Patent and Trademark Office
http://www.uspto.gov/patft/ (25 September 2001).

# Appendix A

## Product Design Specifications (PDS)

## Design Function:

To design a cup and/or a bottle that restricts the amount of liquid that is given to a patient. Ideally we would be able to "set" the cup and/or bottle to dispense a specific volume that is deemed as an appropriate bolus size for the patient. Ages of patients will range from birth to approximately 10 years, but the user of the device may be an adult (*i.e.,* adults may operate device when feeding infants). The goal of this project is to create a therapeutic device that can be used to treat certain swallowing disorders (*e.g.,* aspiration).

## Client Requirements:

1) Device must be able to dispense volumes of liquid in small increments.
2) Materials must meet FDA requirements.
3) Proposed range of volume increments: 1cc-5cc
4) Device should be able to hold up to 8 fl. ounces.
5) Device will be used by children (approx. newborn-10 years old).
6) Adults may need to operate device when children are too young to do it themselves.

## Design Requirements:

### *Physical and Operational Characteristics:*

*Performance Requirements:*

1) Device must be able to dispense volumes of liquid in small increments (approx. 1cc-5cc).
2) Total volume should be about 8 fl. ounces.
3) Operation should be relatively simple, easy to use.

*Safety:*

1) Final design must be able to meet FDA requirements (*i.e.,* food grade materials).
2) Materials must be chemically inert, non-dissolvable, non-irritating.
3) Device must not contain any sharp edges or points.
4) Objects used in design must be large enough to avoid being swallowed by young children.

*Accuracy and Reliability:*

1) Volume increments must be accurate to one cubic centimeter (ideally we should attempt to reduce error as much as possible).
2) Volume increments must be precise to 1cc.
3) Our objective is to minimize these requirements (possibly improve accuracy and precision to 0.1 cc).

*Life in Service:*

1) If used as a home therapeutic tool, device will be used once every 2-3 hours.
2) Device may need to be refilled up to 4 times per feeding.
3) We would like the device to last as long as possible.

*Shelf Life:*

1) Will be stored in a range of temperatures from 50-85 $^{o}$F.

*Operating Environment:*

1) Device will be used in normal indoor conditions (≈ 50-85$^{o}$F).
2) Must be able to withstand fluids with viscosities ranging from water to honey.
3) Device has to be dishwasher safe.
4) Device must be made of materials that possess the durability to withstand normal squeezing and have the ability to return to their normal shape.
5) Device may need handles (perhaps 2) for operator.

*Ergonomics:*

1) Device should feel comfortable inside and outside the user's mouth.
2) No sharp objects.
3) Liquid may be dispensed by a variety of methods (*e.g.* negative pressure from the mouth or pressure from the operators hand or free flowing).

*Size:*

1) Device should be of average bottle weight, perhaps a little heavier due to an adult most likely being the operator of the device (approximately 200-500 grams).

2) All detachable components must be large enough to prohibit swallowing.

*Materials:*

1) Materials must be chemically inert.
2) Non-toxic.
3) Non-dissolvable.
4) FDA approvable.
5) Non-corrosive.

*Aesthetics:*

1) Color should be fairly pleasant to the eye (*i.e.* we should not use ugly green or yellow/brown).
2) Texture should be smooth, but not slippery to the extent where it becomes challenging to hold.

## *Production Characteristics:*

*Quantity:*

1) One for the client, if the device is successful may need to be produced for home use.
2) Eventually each patient may have his or her own device.

*Target Production Cost:*

1) Client prefers the total cost to be no more than $13.00.

## *Miscellaneous:*

*Standards and Specifications:*

1) Must be FDA approvable.

*Customer:*

1) Something that children don't mind using, perhaps even "fun" to use.

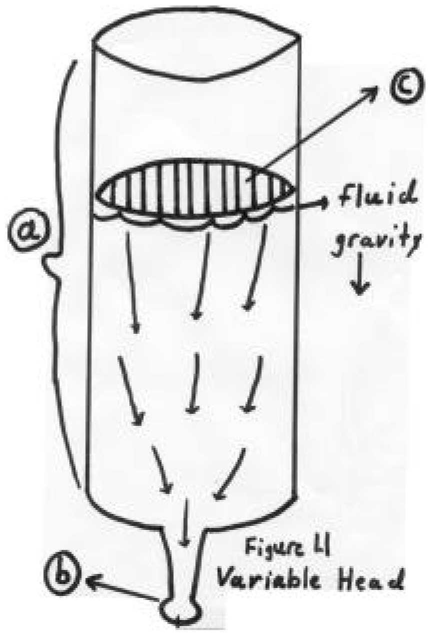


Figure 1. Bottle with variable head to dispense liquid out of pressure sensitive nipple.

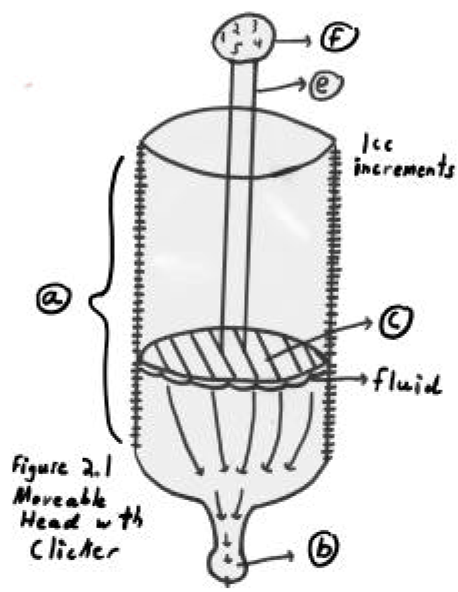


Figure 2. Variable head bottle with clicker and adjustable dispensing volumes.

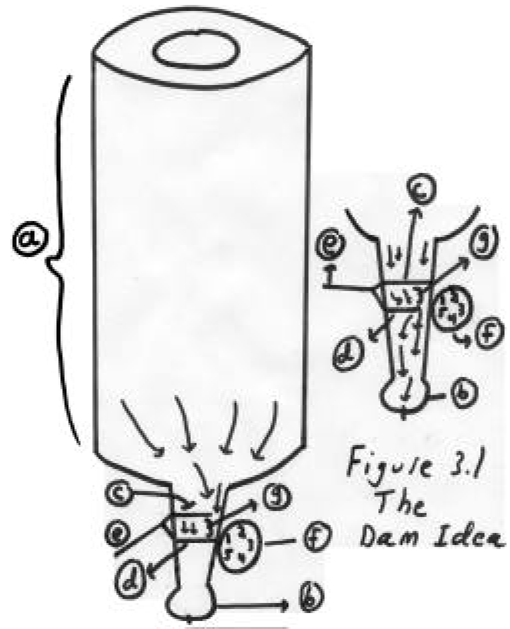


Figure 3-1. Bottle implementing the "dam" mechanism. This lever system allows for accurate volumes to be dispensed upon suppression of one clicker.

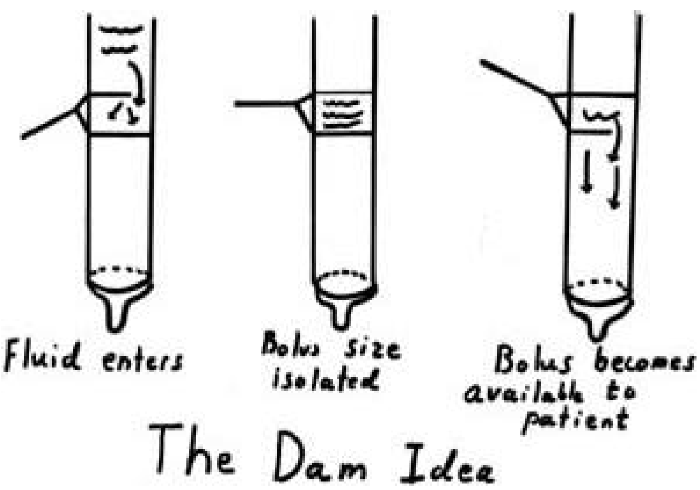


Figure 3-2. Schematic showing the mechanics of the dam idea.

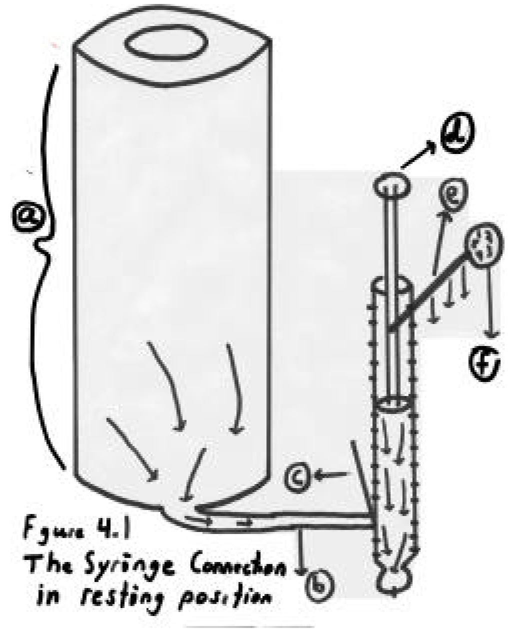


Figure 4. The bottle with a modified syringe connection.

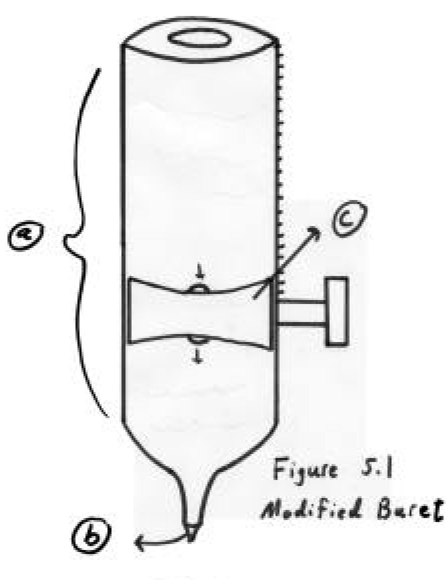


Figure 5. Bottle in the shape of a modified buret.

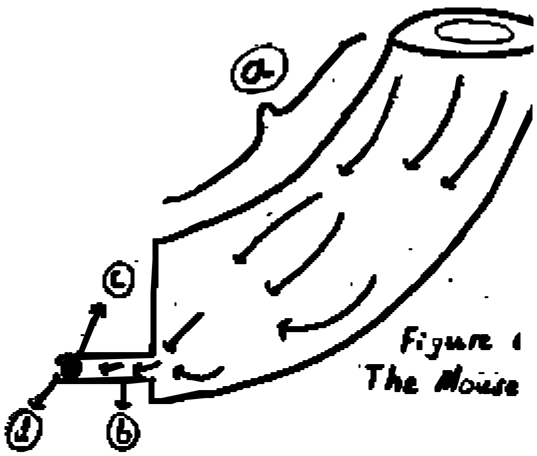


Figure 6. The "mouse bottle" idea.

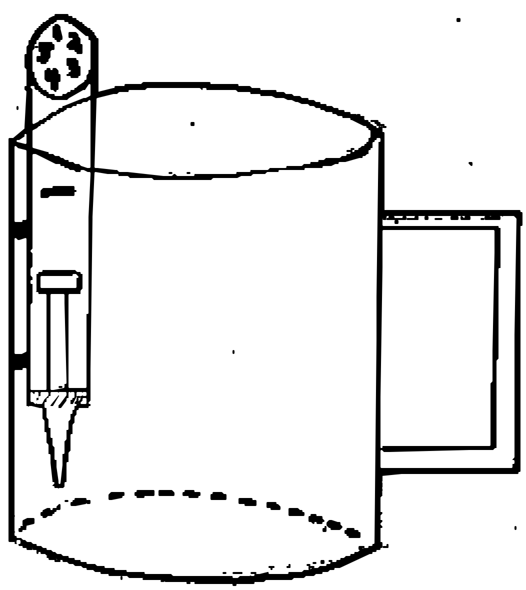

Figure 7. Eppendorf repeater pipetter attached to the inside of a cup.

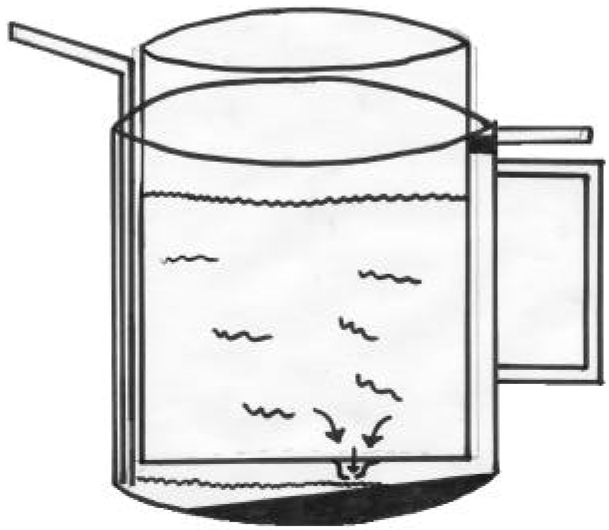

Figure 8. Cup with modified pipetting mechanism. Lever attached near the thumb placement of the handle dispenses liquid when depressed. Straw enables user to access the liquid dispensed in the bottom of the cup.

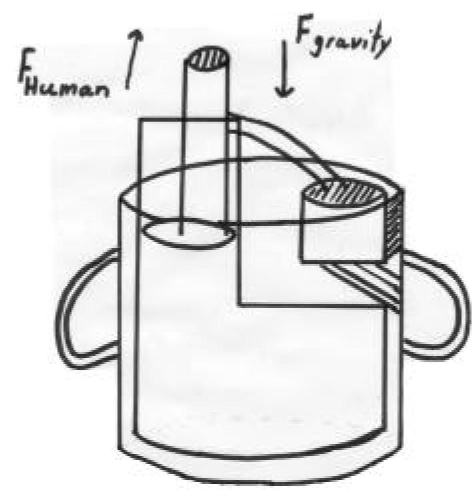


Figure 9. Cup with reagent dispenser attached. Liquid falls into small reservoir and is made available to patient for each sip.