IV DRIP: Intravenous Dehydration Relief in Pediatrics

Category: Technology to Aid Underserved Populations and Individuals with Disabilities

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Abstract

Diarrhea-induced dehydration is the second leading cause of death in children under five years old [1]. Most of these deaths occur in the developing world. Severe dehydration is treated with intravenous (IV) therapy. One risk of IV therapy is over-hydration, which can to lead to severe complications and death. In the developed world, infusion pumps are commonly used to regulate the delivery of IV therapy, but these technologies are too expensive and complex for many hospitals in the developing world. Pediatric wards in these hospitals lack sufficient financial, electrical, and staff resources to monitor children undergoing IV therapy, often causing clinicians to forego treatment entirely.

We have developed IV DRIP—a simple, low-cost, mechanical automatic volume regulator to deliver intravenous fluid in low-resource settings. The device consists of two levers; an IV bag hangs on the upper lever, while a counterweight hangs on the lower, notched lever. The position of this counterweight dictates the volume of fluid dispensed. When the target volume is delivered, the levers tip and kink the IV tubing, stopping fluid flow and thus preventing over-hydration.

Tests have shown that IV DRIP can deliver fluid volumes from 50 mL to 800 mL in 50 mL increments with 97.5% accuracy. Our device is comprised of parts that cost under $80, whereas commercially available infusion pumps cost $1000-$3500. IV DRIP is an affordable, accurate tool to help save the lives of hundreds of thousands of children annually.

Clinical Need

Each year, there are 1.7 billion cases of diarrhea, which lead to the death of 760,000 children [1]. Many of these deaths are the result of severe fluid loss and dehydration, which are treated with IV therapy [2]. Beyond dehydration, there is a range of conditions that require IV fluid, including pneumonia, prolonged high fever, and vomiting. However, one risk of IV therapy is over-hydration, particularly for patients who require small volumes of fluid (100-400 mL), such as children. Over-hydration can lead to edema and death [3].

Figure 1. A child receiving IV fluid from a 1 L IV bag. **John Midturi of the Baylor International Pediatrics AIDS Initiative said, "There is a reluctance to [use] life-saving fluids due to the inability to control the volumes given to patients."**

Due to the risk of over-hydration, the World Health Organization (WHO) recommends that severely dehydrated children are given rapid IV therapy "with close monitoring" [4]. In Africa, many wards are chronically understaffed, with as few as 2.3 physicians and 10.9 nurses per 10,000 patients, making constant patient monitoring difficult [5]. This situation is complicated by the uniform size of IV bags: 1 L bags are most common in the developing world, but these bags are too large for children, who need only a portion of that fluid. Therefore, healthcare providers in the developing world are often reluctant to start IV therapy for patients who require low volumes of fluid (Fig. 1).

In developed countries, infusion pumps are commonly used to deliver IV therapy to pediatric patients; however, these are too complex and expensive for many developing world healthcare settings. Priced at $1000-$3500, infusion pumps require routine maintenance, consumables not generally available in the developing world, and electrical power, which may not be reliable [6]. The dial-a-flow systems that are supplied with standard IV tubing control rate, but not total volume, of delivery.

In field interviews team members conducted last summer, physicians and nurses in district and rural hospitals in Malawi and Lesotho identified the need for a low-cost, mechanical device to limit the volume of fluid delivered during rehydration therapy:

> *Diarrhea is a critical public health issue affecting children in the developing world, and dehydration due to diarrhea can be fatal. The mechanical IV-fluid volume regulator that your students have developed to safely deliver IV fluids would help to effectively treat children suffering from dehydration at Queen Elizabeth Central Hospital and has the potential to save lives throughout the developing world. It is a critical technology for developing world hospitals.*
>
> – Dr. Queen Dube
> Pediatrician at Queen Elizabeth Central Hospital, Blantyre, Malawi

<u>*IV DRIP: Automatic Mechanical IV Regulator*</u>

Our team designed a low-cost, mechanical device to regulate the volume of fluid delivered during IV therapy by monitoring the weight of the IV bag. The IV regulator is entirely machined from readily-available aluminum, steel, and plastic parts that cost less than $80. There are three major components to our device: two linked lever arms, a counterweight, and a spring-powered pincher (Fig. 2). The functionality of these components is driven by the weight-based nature of the device: The position of the counterweight along the notched lever arm specifies the target volume; when this amount of fluid is delivered, the lever arm tips and activates the spring pincher to stop fluid flow. Each notch on the lever arm corresponds to dispensing 50 mL of 0.9% saline, which is the standard treatment for dehydration [7].

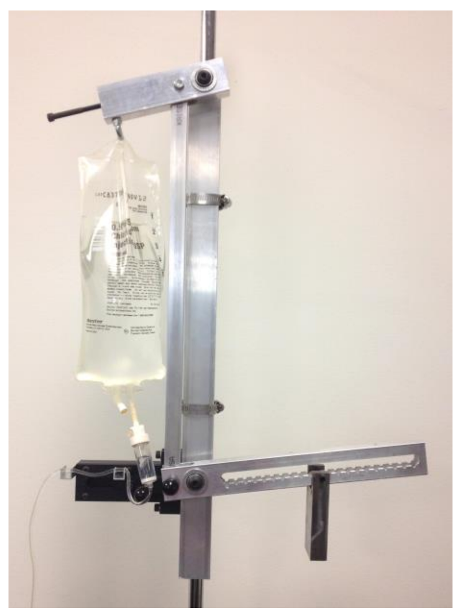

Figure 2. The refined IV DRIP prototype consists of three components that together present a simple user interface that regulates IV therapy.

Usage of our device consists of four simple steps (Fig. 3). The clinician first hangs the IV bag on the device on the hook provided, equilibrates the counterweight, and then moves the counterweight to the notch corresponding to the volume desired. After placing the IV tubing in the holder and setting the spring, the clinician is free to treat other patients because the device not only stops fluid flow at the target volume, but also provides an auditory cue to nearby clinicians when therapy is completed. During the administration of IV therapy, the IV bag loses weight, causing the lever arm system to slowly equilibrate without impeding the flow rate of fluid. When equilibrium is met, the spring activates and kinks the IV tubing shut.

Equilibrating counterweight | Setting target volume (300 mL)

Activating spring clamp | Placing IV tubing

Figure 3. Usage of IV DRIP requires 4 simple steps.

Key Innovations: Weight-based, Entirely Mechanical, and V-shaped Kink

The volume of fluid delivered is measured by monitoring the weight of the IV bag during therapy. By solving two steady-state torque equations that describe the forces acting on the lever arms, we can relate the weight of the IV bag to the volume of fluid delivered. This weight-based measure increases the overall accuracy of the system because we are not constrained by assuming that the flow rate is constant. Moreover, this allows us to extend usage of our device to fluids other than 0.9% saline used for rehydration therapy. Each notch is also calibrated to dispense fluids of other densities, such as: 48 mL of blood, 50 mL of lactated Ringer's, and 44 mL of 5% dextrose. This extended functionality can mimic some usage of regulators such as infusion pumps that are available only in the developed world.

Unlike infusion pumps, our device is entirely mechanical and does not require electricity, a feature that is particularly advantageous in developing countries, where stable electricity cannot be guaranteed. Frequent power outages render infusion pumps and other electrical devices impractical. The mechanical design is based on the use of a single counterweight that has the potential to dispense *any* volume of IV fluid from an IV bag filled to *any* initial starting volume. This flexibility gives clinicians the ability to provide IV therapy to children while eliminating the waste of consumables. Moreover, the user interface resembles that of a physician's scale, in which a mass is moved along a notched lever arm. This design is intuitive to physicians and nurses throughout the developing world, which is especially beneficial due to high staff turnover.

Our device stops fluid flow by inducing a v-shaped kink in the IV tubing, similar to that in a garden hose (Fig. 4). This motion reduces the force applied to the tubing from 15 lb_f used in clamp-based devices to 4 lb_f, which eliminates the risk of rupturing the IV tubing and ensures the sterility of the IV tubing and bag. Since the fluid in the IV bag remains sterile, developing-world clinics can reuse IV bags and reduce cost of treatment. The user also applies a lower force when loading the pincher, which enhances the usability of our device.

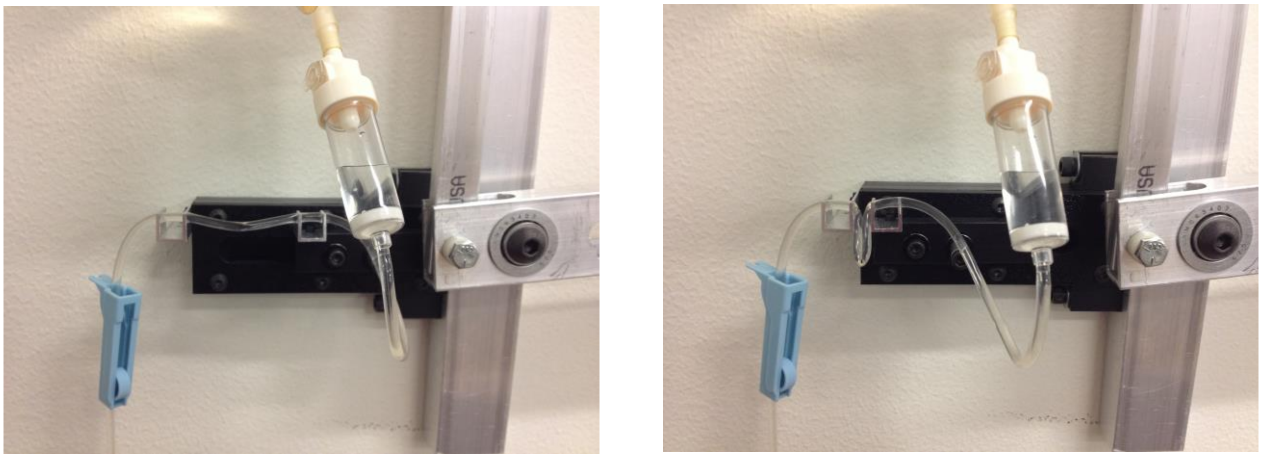

Figure 4. The innovative v-shaped kink reduces the force applied to the tubing while ensuring consistency.

Validation

Preliminary data from a previous iteration indicate that IV DRIP can deliver volumes across the clinical range of 50 mL to 800 mL in 50 mL increments with 97.5% accuracy (Fig. 5). The maximum deviation of 18 mL demonstrates that there is almost no risk of over-hydration. This error is well within the clinician-specified target average error of less than 10%.

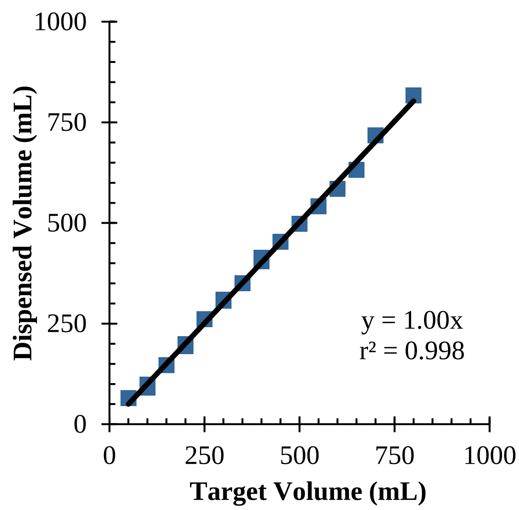

Figure 5. IV DRIP accurately dispenses fluid throughout the clinical range.

The ease-of-use of IV DRIP has been confirmed in field interviews with American, Malawian, and Basotho health professionals. Clinician feedback is typified by praise for the device design: “an elegant solution to a pressing problem” (Soumyadipta Acharya of The Johns Hopkins University). We plan to verify this with a standard system usability survey with Malawian clinicians in Summer 2013.

Durability of our device has been confirmed by ensuring functionality after approximately 1000 uses for a previous iteration. In particular, the tubing holder and spring pincher were tested by mounting IV tubing, setting the spring clamp, and kinking the IV tubing. We can assume that the spring pincher is the least durable component of our device because it undergoes the greatest amount of movement of all components. IV DRIP can successfully stop fluid flow after 1000 uses, which would simulate usage for 10 years assuming that the device is used twice weekly.

We have secured $40,000 in grant funding from the National Collegiate Inventors and Innovators Alliance, the Rice Center for Engineering Leadership, and the Oshman Engineering Design Kitchen, along with $15,000 in support from the Rice 360^{o}: Institute for Global Health Technologies, in order to continue testing the IV DRIP device over the next 18 months. We plan to perform extended tests confirming the accuracy of our device in Houston and further assessments of its usability in Malawi this summer. This October, two members of the team will travel to Liberia to perform market research and to engage hospital administrators, additional clinicians, NGO representatives, and Ministry of Health officials.

Conclusions

IV therapy can help save the lives of over 760,000 children who die annually due to dehydration. However, children in developing countries often do not have access to the life-saving IV therapy they need because clinicians cannot regulate the volume of fluid delivered to them. We have developed IV DRIP, a low-cost, mechanical volume regulator that is both accurate and robust. By combining a durable design with an intuitive, mechanical interface, IV DRIP provides clinicians with an indispensable tool to significantly improve patient outcomes and reduce pediatric mortality.

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