

GLOBAL HEALTH

Innovation Insight Series



The DoseRight syringe clip

Photo courtesy of 3rd Stone Design

DOSERIGHT II: Transitioning to High-Volume Production

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THE PROBLEM/SOLUTION SPACE

Accurate dosing is essential when liquid medications are given. It is particularly crucial for patients with HIV/AIDS, because incorrect dosing of anti-retroviral medications (ARVs) can create viral drug resistance. Infants and children are particularly vulnerable to medication errors because they are physically small, have immature livers and kidneys, and less robust immune systems. As a result, there is a significantly increased rate of medication error resulting in harm or death in pediatric patients (31 percent), as compared with adult patients (13 percent).^{1,2} Yet studies show that 40-60 percent of parents and caregivers make dosing errors when giving liquid medication to their children.^{3,4}

The variety of available dosing implements adds to the potential for miscalculation. Dosing spoons/ cups, droppers, and oral syringes can be difficult to read, and vary in their

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increments, units of measure, and volume. Although measurement errors are prevalent in developing and developed countries alike, they are most likely to occur in environments where caregivers have low reading and numeracy skills.⁵

ABOUT THE DOSERIGHT™ SYRINGE CLIP

At Rice University, the Rice 360° Institute for Global Health Technologies seeks to design and implement technologies that improve health and reduce poverty. Beyond Traditional Borders (BTB) is Rice 360°'s undergraduate educational program. As part of a multi-disciplinary curriculum, BTB challenges students to develop innovative, low-cost technologies that meet specific healthcare needs in developing countries.^{6,7}

One promising student innovation that emerged from the BTB program was the DoseRight Syringe Clip. Designed to enhance the dosing accuracy of liquid ARV medications in resource-limited settings, DoseRight was a simple plastic clip inserted into the top portion of a standard oral syringe. By acting as a stopping mechanism, the clip controlled the amount of medication that could be drawn into the syringe. Produced in varying lengths to correspond to different dosing volumes, the clips could be quickly and easily affixed to ensure dosing accuracy regardless of caregiver literacy or visual acuity.



DoseRight comes in 10 different sizes that are color-coded by dosage volume

Using prototypes fabricated in-house, BTB faculty and students had completed studies and field tests that verified a significant increase in dosing accuracy when the clip was used. They had also lined up DoseRight's first customer. The Clinton Health Access Initiative (CHAI), a leader in global efforts to treat children with HIV/AIDS,⁸ was eager to become a partner/customer of the technology. At that point in the product development process, BTB licensed the DoseRight concept to 3rd Stone Design, a privately-

held product design, strategy, and development consultancy. Headed by CEO Robert Miros, 3rd Stone design was a for-profit company with a secondary focus on commercializing healthcare products for low-resource settings in developing countries.

ONE CHALLENGE: TRANSITIONING TO HIGH-VOLUME PRODUCTION

When 3rd Stone Design took over the project, Miros acknowledged that the BTB team had achieved "some good results."⁹ The preliminary CHAI order for 200,000 clips to be distributed in Swaziland, Africa via the Ministry of Health was particularly encouraging. However, the technology was not ready to be manufactured at this volume.

As Miros explained, educational programs tended to focus on the more exciting aspects of early-stage design, including needs finding, concept generation, prototype development, and preliminary bench and field testing. In the process, they often underemphasized the importance of issues related to manufacturing and industrial engineering. Accordingly, while many student teams can successfully design and produce small numbers of prototypes for testing under controlled circumstances, they lack the expertise to design for mass production and create products that perform as intended when implemented outside a study environment. "They are coming from a largely theoretical training so the basics of manufacturing are often not at the top of mind—I mean to get a factory set up,

to have the right sort of drawings and quality documents and inspection criteria,” Miros commented. “There’s a lot of hard work that goes into making something that’s consistently high quality and low cost.”

With DoseRight, the BTB student innovators had created their prototypes using 3D printers that allowed them to essentially print the clips out of colored plastic. Although this process enabled them to complete a proof-of-concept, it was not cost effective for any sort of high-volume production. “Even if they could have made 200,000, which they really couldn’t have with that technology, it probably would have cost them a dollar apiece,” said Miros. With CHAI eager to procure the clips, 3rd Stone needed to modify the product to support the necessary ramp-up in production.

THE SOLUTION: DESIGN FOR MANUFACTURABILITY

According to Miros, the ability to take an idea or prototype and transform it into a manufacturable product was one of the most essential steps in the innovation process. “That’s not to say the idea is the easy part,” he said. “But there are a lot of needs and a lot of potential ideas. The challenge becomes how do you take that initial idea, scale it up, and make it into a real product?” He emphasized the fact that these challenges are particularly acute in the field of global health, where costs must be kept incredibly low in order for the product to be affordable in resource-constrained settings. “You have to ask yourself, after you’ve done all the hard work, does the cost still make sense?” Healthcare providers in developing countries, or even the nongovernmental organizations (NGOs) that might be the actual purchasers of a technology, simply cannot pay very much. And so, in order to keep the unit cost at the lowest possible level, “You have to be really good at figuring out the manufacturing,” he said. Innovation teams emerging from the university environment needed to ensure that they developed strong competencies in design for manufacturing, either by adding experienced individuals to the group or by contracting with a seasoned partner.

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For DoseRight, 3rd Stone’s primary challenge was figuring out manufacturing. Injection molding offered a lower-cost alternative to 3D printing that would produce high-quality results. With this process, heated polymers were forced into a multi-part mold that was essentially a negative form of the desired part. The mold was opened after cooling and the finished part was ejected.¹⁰

Given its simple design, molding the part would be relatively easy. However, the DoseRight clips needed to be produced in 10 different lengths in order to provide dosing volumes from 0.5 mL to 5.0 mL in half mL graduations. Normally, this would require the creation of 10 different molds. The 3rd Stone Design team estimated that 10 hard tooling molds (made of hardened steel for large-quantity production) would cost \$200,000-\$300,000—far too much for a product in start-up mode. Tooling costs had to be held to a fraction of that in order to keep the capital investment reasonable, and to produce the clips at a cost that global healthcare customers could afford to pay while maintaining the quality of the finished clips.

3rd Stone Design solved the problem by designing a limited mold set based on multiple inserts of varying size that enabled them to produce high quality parts at a reasonable cost. While this solution did not bring the cost down to a few pennies per clip (which is the ultimate goal), it was a good start. As the first customer for the DoseRight clips,



The DoseRight syringe clip after final manufacturing

CHAI understood that it would have to pay slightly more for the product initially, with subsequent costs likely to decrease as production volume rose. “The customer had been coached, a little bit, on what the initial pricing would be, and we were able to hit that price and still have some profit in it; not a lot. And again, our expectations are different when it’s a design for a global health, or low-resource setting product,” Miros emphasized. “We pull back our expectations a lot.”

Using the limited mold set, 3rd Stone was able to cost-effectively manufacture all ten lengths of the DoseRight clips in a quality-controlled environment, with all parts bagged and labeled in a manner appropriate for medical disposables. The final products were made of polypropylene, embossed with the dosage achieved by the specific clip, and color-coded for easy differentiation of size and dosage. In August of 2011, in partnership with CHAI, Swaziland’s Ministry of Health began distributing more than 200,000 dosing clips as part of its Prevention of Mother to Child Transmission of HIV/AIDs program.

3rd Stone subsequently went on to pursue additional orders in developing countries, working with large NGOs and local ministries of health that were running, or planning, countrywide vaccination programs. In the U.S., 3rd Stone planned to seek FDA clearance requirements and market DoseRight as a device to improve accurate pediatric dosing of over-the-counter medications. 3rd Stone’s likely approach in first world countries was to pursue an OTC strategy, either through national chains that already sell oral syringes for dosing pediatric medicines, or through large healthcare providers with technology acquisition programs. ♦

NOTES

- 1 “DoseRight Syringe Clip Fact Sheet,” Rice University Beyond Traditional Borders, <http://cohesion.rice.edu/collaborations/btb/emplibrary/DoseRight%20Syringe%20Clip.pdf> (July 16, 2012).
- 2 “Small Patients, Big Consequences in Medical Errors,” The New York Times, September 16, 2008, <http://www.nytimes.com/2008/09/15/health/healthspecial2/15mistakes.html> (July 17, 2012).
- 3 H.S. Yin, B.P. Dreyer, L. Van Schaick, G.I. Foltin, C. Dinglas, A.L. Mendelsohn, “Randomized Controlled Trial of a Pictogram-Based Intervention to Reduce Liquid Medication Dosing Errors and Improve Adherence Among Caregivers of Young Children,” *Archives of Pediatric Adolescent Medicine*, 2008, 162 (9), pp. 814-822, <http://archpedi.jamanetwork.com/article.aspx?articleid=380096> (July 17, 2012).
- 4 H.K. Simon, D.A. Weinkle, “Over-the-Counter Medications: Do Parents Give What They Intend to Give?” *Archives of Pediatric Adolescent Medicine*, 1997, 151 (7), pp. 654-656, <http://archpedi.jamanetwork.com/article.aspx?articleid=518421> (July 16, 2012).
- 5 H.S. Yin, B.P. Dreyer, L. Van Schaick, G.I. Foltin, C. Dinglas, A.L. Mendelsohn, “Randomized Controlled Trial of a Pictogram-based Intervention to Reduce Liquid Medication Dosing Errors and Improve Adherence Among Caregivers of Young Children”, *Archives of Pediatric Adolescent Medicine*, 2008, 162 (9), pp. 814-822, <http://archpedi.jamanetwork.com/article.aspx?articleid=380096> (July 17, 2012).
- 6 About Us,” Rice 360°, <http://www.rice360.rice.edu/content.aspx?id=34&linkidentifier=id&itemid=34> (July 16, 2012).
- 7 “Education,” Rice 360°, <http://www.rice360.rice.edu/content.aspx?id=617&linkidentifier=id&itemid=617> (July 16, 2012).
- 8 “About CHAI,” Clinton Health Access Initiative, <http://www.clintonhealthaccess.org/about> (July 19, 2012).
- 9 All quotations are from an interview with Robert Miros conducted by the authors unless otherwise cited.
- 10 “Injection Molding,” R&D Molders, Inc., <http://www.rdmolders.com/injection-molding/> (July 26, 2012).

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