In addition to the 3D printed face mask, a model for inverse silicone forming was also created in order to more closely mimic the original face mask and facilitate large-scale production. PHOTO COURTESY USPHS

Saving Lives with 3D Printing

To educate the public on opioid overdose prevention, health officials in the State of Maryland developed a hands-on training program, but when the cost of training kits slowed expansion of the effort, engineer officers with the U.S. Public Health Service turned to 3D printing and silicone molding technologies to solve the problem.

By Cdr. Leo Gumapas, P.E., M.SAME, USPHS, Lt. Timothy Martin, Ph.D., USPHS, and Cdr. James Coburn, M.SAME, USPHS

According to the Centers for Disease Control & Prevention, more than two million people in the United States struggled with an opioid use disorder in 2016. Rates of opioid overdose deaths rapidly increased to over 70,000 in 2017. Opioids are a class of drugs that include prescription pain relievers, heroin, and synthetic opioids such as fentanyl. If taken differently than prescribed, opioids can cause death by slowing, and eventually stopping, a person's breathing.

In response to this nationwide epidemic, Vice Adm. Jerome Adams, USPHS, the 20th Surgeon General of the United States, issued an Advisory on Naloxone and Opioid Overdose in April 2018 urging more Americans to carry naloxone, a lifesaving medication that can immediately, but temporarily, reverse the effects of an opioid overdose—namely the dire risk of slowed or stopped breathing.

MEDICAL DEVICE APPROVAL

In 2015 and 2016, the Food & Drug Administration approved two of the first-ever medical devices to deliver naloxone. During an opioid overdose event, naloxone must be administered immediately, but many individuals do not know the signs of an opioid overdose, the benefits of naloxone, or how to administer it. For the solution to work on a large scale, it is critical for the public to not only carry naloxone, but to know when and how to use it.

Those in service to public health began to address this knowledge gap by providing public training on opioid overdose prevention. Commissioned Corps officers of the U.S. Public Health Service partnered with the Maryland Department of Health to train individuals in the community on how to administer naloxone. Over 100 Commissioned Corps officers were trained and certified to provide naloxone training.

Due to constrained resources, however, the Department of Health could not purchase additional training kits and so training had to be limited. Over 70 percent of the cost of each naloxone training kit is attributed to CPR training face masks, an essential piece to providing hands-on training. Rather than purchase additional face masks, however, Public Health Service engineer officers partnered with the Food & Drug Administration's 3D Printing Core Lab to develop the first-ever 3D printed face mask and an inverse silicone molded mask as cost-effective alternatives.

LEVERAGING TECHNOLOGY

The face mask model was created by first using a laser scan to digitally capture the surface of a face. This scan provided a template to construct a solid digital model by trimming the edges and thickening the body. An anatomically accurate 3D model of the nasal passages, derived from a human MRI scan, was then spliced in.

Next, the 3D face model underwent several design iterations to meet the end-user requirement of being used to train laypersons on how to administer naloxone. Design changes included changes to the amount of exposed face area, nostril thickness, presence or absence of a septum, material type, and print settings. These changes optimized the insertion force of the naloxone device and handling characteristics based on functional testing by naloxone trainers and anatomical assessment by an otolaryngologist.

The model was 3D printed using a flexible filament material and minimal infill for pliability and structural integrity. It was designed to be printed upside-down in order to eliminate post-processing and enable printing from almost any 3D printer. (The model and printing parameters are publicly available for download on the National Institutes of Health 3D Print Exchange.)

AN ALTERNATIVE TECHNIQUE

As an alternative to the 3D printed face mask, Commissioned Corps engineers also developed and refined a mold and molding technique for fabricating silicone face masks. The silicone face mask is intended to more closely mimic the original training kit's face mask and facilitate larger scale production. The digital design of the mold was made by removing the intersection of a block and the digital 3D face model. The cut surface was refined to eliminate overhangs and facilitate mold release. The mold was printed using a polyamide material (Nylon 12), and the silicone face masks used a two-part liquid silicone rubber, which cures to a flexibility of 30A hardness, or about as stiff as a pencil eraser.

The silicone face mask fabrication process starts by mixing the liquid silicone rubber, pouring it into the bottom half of the mold, pressing the top half of the mold into the bottom half, and clamping shut for about six hours. Then the mold halves are separated and the flashing portion trimmed away.

Several changes to the mold and molding technique were made to optimize the silicone face mask. To improve its appearance, a pressing technique was used to reduce bubbles and crevice features. In order to eliminate pockets of missing material, at least 6-oz of liquid silicone rubber was used. To facilitate removal of the cured silicone face mask from the mold, the hook area inside each nostril was trimmed away.

Future improvements to the mold include adding alignment pins between the mold halves, reinforcements on the casing for clamping, and an increased thickness to the mold areas related to the outer edge of the face. (Once revised, the mold will be uploaded to the National Institutes of Health 3D Print Exchange with a link to a training video on how to use it to fabricate a silicone face mask.)

AN EFFECTIVE SUBSTITUTE

A pilot test in 2019 of more than 200 individuals found that both the 3D printed and silicone molded face masks were effective substitutes. Survey data from trainees affirmed the hands-on portion of the program to be very useful in helping them understand how to intranasally administer naloxone.

With the new face masks, the cost of training kits was reduced by 90 percent. By increasing accessibility of naloxone training kits, Public Health Service engineers will help communities across the nation inexpensively procure training kits and replicate a local naloxone training program based on the framework developed by Maryland public health officials.

Through their professional commitment to the public health, Commissioned Corps officers are bolstering knowledge and resiliency against the deadly opioid epidemic.

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