Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

3D Printed Nasopharyngeal Swabs for COVID-19: Innovations and Lessons Learned†

HARVARD MEDICAL SCHOOL

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Addressing the swab crisis

In early 2020 the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic caused a **severe shortage of nasopharyngeal swabs**, which are required for collection of optimal specimens, creating a critical bottleneck blocking clinical laboratories' ability to perform high-sensitivity virological testing for SARS-CoV-2.

Through an innovative, multidisciplinary, cooperative, rapid-response translational-research program, **we emergently developed and clinically validated new swabs** for immediate mass production via the method of **3D printing.**

Lessons learned

1: Define the mission

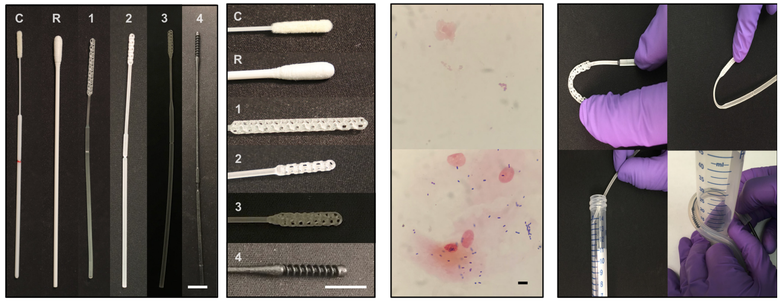
2: Establish norms

3: Leverage expertise

4: Communicate clearly

5: Stay positive!

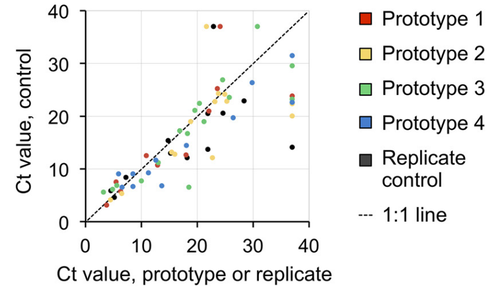
Creating & testing new swabs

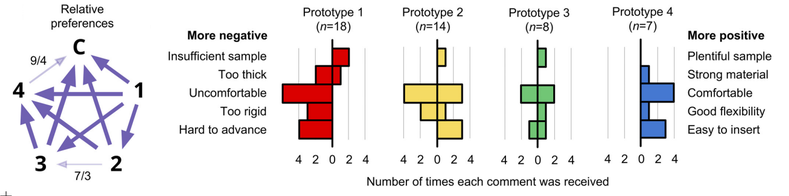


We performed a detailed multistep preclinical evaluation of **160 swab designs** and 48 materials from 24 companies, laboratories, and individuals. We created a **public data repository on GitHub** to share results and feedback. We validated **four prototypes** through an institutional review board (IRB)-approved clinical trial that involved **276 outpatient volunteers** who presented to our hospital's drive-through testing center with symptoms suspicious for COVID-19. Each participant was **swabbed with a reference swab (the control) and a prototype**, and SARS-CoV-2 reverse transcriptase PCR (RT-PCR) **results were compared.**

Clinical performance

All prototypes displayed **excellent concordance with the reference (κ = 0.85 to 0.89)**. Cycle threshold (CT) values were not significantly different between each prototype and the control, supporting the new swabs' noninferiority ($p \leq 0.05$). Study staff preferred one of the prototypes over the others and preferred the control swab overall. The **total time elapsed between identification of the problem and validation of the first prototype was 22 days.**





†Callahan et al. *JCM* 58:e00876 2020; Arnaout *JCM* 59:e01239 2021