Opening Up New Supply Chains

CORRESPONDENCE

COVID-19 NOTES

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Opening Up New Supply Chains

The Covid-19 pandemic has forced health care providers to dramatically increase their use of swabs, protective gear, ventilators, and other medical devices. This rapid increase in demand, coupled with the destabilizing effect of the crisis on society and the global economy, has disrupted normal sources of supply and led to critical shortages. Such shortages threaten the ability of clinicians and public health officials to conduct testing for Covid-19 and to care for infected patients. In response to these challenges, the Massachusetts Technology Collaborative (MassTech), a state economic-development agency with a mission of strengthening the Commonwealth's tech and innovation economy, formed the Manufacturing Emergency Response Team (M-ERT). Within days, the M-ERT mobilized to help Massachusetts-based manufacturers open up new supply chains to start producing materials needed to fight the epidemic.

MassTech officials assembled a diverse group, with volunteers from university research-and-development and engineering departments, manufacturing companies, and health care institutions, that convened three times each week to develop new supply chains for vital materials. The barriers for manufacturers to begin producing these materials were high. Every device used in health care must comply with Food and Drug Administration (FDA) regulations and other specifications associated with its product code and classification that are designed to ensure safety and efficacy. These guidelines have rapidly evolved; the FDA has released multiple guidance documents and emergency-use authorizations in recent weeks to help manufacturers respond quickly to Covid-19 (https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents; https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe). Retooling, ordering new materials, and establishing markets for new products is risky and expensive, so companies needed guidance to address uncertainties regarding the level of demand to expect for products and the corresponding amount of capital investment required for new equipment and their workforce. The M-ERT also faced uncertainty about which materials were needed immediately and which manufacturers would be able to meet the most urgent needs in time to alleviate shortages.

The M-ERT tackled each of these problems. Frequent discussions with the FDA allowed team members to develop and share a data repository containing information on relevant emergency policies and regulations. Volunteer leaders became experts in each product area and were in constant contact with would-be manufacturers to help manufacturers understand current guidelines and to mitigate roadblocks. The M-ERT partnered with organizations including the University of Massachusetts Lowell, the Massachusetts Institute of Technology's Lincoln Laboratory, and Advanced Functional Fabrics of America to establish complex testing procedures for fabrics, gowns, face shields, masks, and swabs. In the case of nasopharyngeal (NP) swabs, three-dimensional (3D) printing and other processes were explored, materials were tested, and clinical validation was completed at Beth Israel Deaconess Medical Center (BIDMC) under protocols approved by an institutional review board (https://www.washingtonpost.com/climate-environment/2020/04/22/nasal-swabs-shortage-coronavirus). These testing approaches have led to rapid FDA registration of new products that comply with existing or emergency regulatory requirements, including at least four kinds of swabs that can be mass produced by

means of 3D printing at a potential rate of millions of swabs per day (https://printedswabs.org/), multiple types of personal protective equipment (PPE), and other devices.

To ascertain levels of demand for various products, the M-ERT consulted purchasing officials at BIDMC and other institutions. The team is now assessing the amount of PPE and other materials that will be needed throughout Massachusetts in the coming year. The Commonwealth has helped prime the pump by placing strategic orders for goods, including 3 million gowns, to enable these Massachusetts-based supply chains to become permanent. Manufacturers also sell products directly to health care providers, first responders, and other buyers.

To date, the M-ERT has helped develop domestically produced supplies of NP swabs, face shields, isolation gowns, face masks, and sanitizers. It also has accelerated the production of new ventilators, is helping to establish a domestic source for ventilator filters, and created a plan for rapid servicing of ventilators. Most important, by linking and facilitating communication between manufacturers, engineers, regulators, health care providers, and other buyers, the M-ERT has established a trusted supply chain and assured that people who care for patients with Covid-19 in the Commonwealth don't lack supplies for testing, patient care, and protection. Similar partnerships may be possible in other states to assure that health care providers, first responders, and other residents all have the essential supplies they need.

Mark L. Zeidel, M.D.

Beth Israel Deaconess Medical Center
Boston, MA

Carolyn Kirk, B.A.

MassTech Collaborative
Westborough, MA

Ben Linville-Engler, S.M.

Massachusetts Institute of Technology
Cambridge, MA

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