Disaster Preparedness and Response

A COMPRENDIUM OF BEST PRACTICES FROM THE HEALTHCARE INDUSTRY
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When a large-scale catastrophe strikes — be it a pandemic, a hurricane, or any other disaster that threatens lives and health — Americans must have the confidence that the nation’s private and public sector infrastructures are prepared to respond to the challenge and to direct essential assistance where and when it is needed most.

The Healthcare Leadership Council, an alliance of leading companies from all health sectors, is taking steps to strengthen that public confidence through two important initiatives. The first is a joint project with the Duke-Margolis Center for Health Policy, with contributions and input from dozens of organizations with disaster preparedness and response expertise, to develop a comprehensive framework for private-public collaboration that better prepares our nation for future public health crises.

The other initiative is this compendium. Few Americans have the opportunity to see what happens behind the scenes at major healthcare companies to enable rapid response when catastrophe strikes. This publication details best practices among Healthcare Leadership Council member companies in disaster readiness and response.

In these pages, you will see how organizations ranging from hospitals and health systems to pharmaceutical manufacturers, from medical technology innovators to national healthcare distributors and leaders from other health sectors have leveraged their resources, expertise, and experience in crisis management to create sustainable approaches that will protect public health in times of extraordinary stress. The examples in this compendium concern responses to COVID-19 as well as previous major disasters.

Our hope in sharing these examples is that they can serve as both inspiration and instruction, providing templates for the types of actions that can be taken to strengthen health security for the American people. While we cannot predict what the future might bring, the full breadth of the healthcare industry, working with our partners in all levels of government, is committed to protecting public health against any and all challenges that may come our way.

Mary R. Grealy
President
Healthcare Leadership Council

Calvin Schmidt
SVP & Worldwide Leader, Government Affairs & Policy
Johnson & Johnson
Chairman, HLC Task Force on Patient Safety and Quality
Introduction

In 2019, the HHS Assistant Secretary for Preparedness and Response met with Healthcare Leadership Council members to discuss the need for a private-public collaborative effort to prepare for and respond to major disasters. The decision to engage in this effort turned out to be a sound one as, a year later, the federal government and private sector healthcare companies found themselves dealing with a worldwide pandemic of historic magnitude.

The COVID-19 response has underscored the multifaceted nature of readiness and response. It’s about ensuring the capability to deliver timely, high-quality care, whether in person or virtually. It’s about identifying and exchanging the data necessary to make sound decisions and project future challenges. It’s about protecting and strengthening the healthcare supply chain so that essential tools, materials and personnel are in the right place at the right time when they are needed most. It’s about developing breakthrough treatments and vaccines. And it’s about having a private sector disaster response infrastructure that can interact seamlessly with public health authorities.

The following pages outline the various actions that leading private sector companies have taken to respond to recent public health crises, including COVID-19 and natural disasters. Lessons learned from previous challenges are strengthening the industry’s response to future threats. Our healthcare system is continually utilizing the best innovative thinking to answer the call during the worst of times. This compendium tells the story of an industry that’s continually preparing for the unthinkable and putting plans in place to protect lives and health.
COVID-19 Disaster Preparedness Success Stories

Telehealth
Among the list of innovative services that AdventHealth has launched during the COVID-19 pandemic are video visits used to provide additional comfort and convenience for patients. Video visits, also known as telehealth appointments, are virtual appointments with medical providers. By using this service, patients can receive care from AdventHealth via video — such as through the AdventHealth app or other video chat service — or by phone.

AdventHealth purchased more than 900 Chromebooks to distribute to patients at its Central Florida hospitals. Patients who don’t have access to a smart device can use them to have one-on-one face time with their family and friends through a variety of apps. The Chromebooks are available to all patients, but have been especially useful for low-income families or seniors who don’t have access to a smart device.

Virtual Family Visitation
The notoriously contagious virus pushed nearly every healthcare provider across the country, including AdventHealth, to enact strict family visitation policies. While AdventHealth still allowed a single visitor for individuals in labor, pediatric patients, and in end-of-life events, the organization put a firm lid on other types of visitation in an effort to contain virus spread. However, keeping patients separated from their families while they recovered from COVID-19 or another serious illness was not an option.

Within 48 hours, the patient experience and health IT teams were able to distribute about 1,000 Chromebooks across the nine-state health system. Through a deep partnership between AdventHealth and Google, the health IT team was able to build a system that was easy for patients, clinicians, and patient experience leaders to use. This program has been an asset for AdventHealth and will continue to promote a positive and empathic patient experience even after medicine stamps out COVID-19. For more details, click here.

Remote Patient Monitoring
AdventHealth uses Remote Patient Monitoring (RPM) in Emergency Departments (EDs) across its hospitals to track the health of COVID-19 patients after discharge. Patients have been discharged and sent home with a telecommunication device to answer daily questions about symptoms and record their temperature. By monitoring patient data from wearables and other diagnostic tools, AdventHealth has been able to monitor the health of patients from the safety of their homes.

COVID-19 Vaccine Clinical Trials
AdventHealth is administering sarilumab as part of a clinical trial to determine the drug’s effectiveness against COVID-19. Since its normal function is to reduce inflammation in the joints, the hope is that it will have a similar benefit in reducing the inflammatory response in the lungs of severely ill COVID-19 patients. Clinical trial participation is just one part of a broad effort to bring innovative solutions to the fight against COVID-19.

AdventHealth has also been selected as a testing site for the Janssen Pharmaceutical of Johnson & Johnson’s Phase 3 clinical research study to evaluate the safety and efficacy of an investigational COVID-19 vaccine candidate. Called Ensemble, the vaccine trial is a part of the federal “Operation Warp Speed” effort to test and approve a COVID-19 vaccine.
The AdventHealth Research Institute Team aims to enroll 4,500 participants over an 8-week period. A key aim of this study is to enroll a diverse population of participants, including African Americans, Hispanics, seniors, and frontline workers, including health care workers. Enrollment is currently under way online. More information about the trial is available at AdventHealthVaccineTrials.com.

Communications
In an effort to better inform the public, AdventHealth launched regular roundtable discussions with clinical experts on issues such as the impact of COVID-19 on children and pregnant women, the appropriate use of face masks and other safety measures. These discussions have been streamed in social media platforms, allowing the public to ask questions live.

Patient Safety
AdventHealth launched a variety of efforts to ensure the safety of patients and team members during the COVID-19 pandemic. Their teams were prepared to put new protocols in place that added measures of cleanliness and amplified key processes the health system already had in place.

The basic steps included limiting visitors, taking temperatures and reducing the number of patients in waiting rooms. Additional steps required innovation: scanners that take temperatures when walking through hospital campuses; robots that emit UV light to clean patient rooms, ambulances and even personal protective equipment; aerosols that attach to any surface to eradicate the virus; and foot sanitizers that also use UV light to kill the virus on the soles of shoes. The technology combines ozone and ultraviolet rays to eliminate these germs.
Continuity and Recovery Planning

In the event of a business disruption, BCPs are designed to help us to continue operation of critical business functions, such as processing customer orders, maintaining regulatory compliance and distributing goods and supplies to customers and patients. Depending on the affected business unit(s), continuity strategies may include:

• Relocating impacted businesses to designated response and recovery locations;
• Using redundant processing capacity at other locations;
• Designing our technology and systems to support the response and recovery processes for critical business functions;
• Adopting a communication plan to ensure that AmerisourceBergen’s customers and associates receive emergency notifications and instructions via a variety of sources and channels.

As part of our resilience program, ABC identifies the applications that are critical to each of our business divisions. Robust backup, replication and archiving strategies have been implemented to protect our data, and we have established IT Service Continuity Plans to address high availability and disaster recovery for designated critical systems.

To ensure a continuous state of readiness, all resilience-related plans are required to be reviewed, tested and maintained on an annual basis to ensure that documented information is current and recovery strategies support our operational objectives.
ABC enterprise resilience strategies are designed to respond reasonably and effectively to events of varying scope, including business disruptions that may be internal to ABC as well as larger widespread disruptions that affect entire geographic regions. Because the timing and impact of disasters and disruptions is unpredictable, we have to be flexible in responding to actual events as they occur.

ABC has a long and proud history of resilience during disruptive events — from local occurrences, such as power outages, through larger events like hurricanes — that demonstrates both our commitment to excellence in business resilience and our ability to serve our customers and patients.

Although we have taken significant steps to develop and implement sound business resilience plans, we cannot guarantee that systems and business functions will always be available or recoverable after a disaster or significant business disruption. However, we believe that our planning for such events is robust and consistent with many of the best practices established within the industry. Any material changes to the above information will be made available upon request.

Because of the confidential and proprietary nature of the material they contain, ABC does not share its business resilience plans with individuals outside the organization. Under certain circumstances, and with non-disclosure agreements (NDAs) in place, ABC is willing to provide summary information or meet with parties interested in discussing specific parts of the policies and plans.

If there are further questions regarding our business resilience program, please contact an AmerisourceBergen Account Representative or the Global Business Resilience Office.

The information contained in this disclosure is provided for informational purposes only. Nothing contained herein shall be construed to amend, supplement or otherwise modify any of the terms and conditions set forth in any customer agreement.
Every Patient, Every Time - That's Our Mission and Our Legacy

Amgen is one of the world’s leading biotechnology companies. We are a values-based company, deeply rooted in science and innovation to transform new ideas and discoveries into medicines for patients with serious illnesses. Over the years we have built a resilient manufacturing and supply chain to ensure our patients suffering from serious illness always receive their medicine. We are very proud of the fact that since this measure of drug shortages was tracked in 2007, Amgen did not have to report any drug shortages to agencies. This legacy continues despite the increasing frequency of supply chain interruptions such as hurricanes, earthquakes, fires, and now through the COVID-19 pandemic. Following our values, we can confidently say that we do not anticipate any drug shortages or disruptions of our commercial products during these times of disruption.

This is based on our holistic risk management approach, which we call "Supply Resilience." Supporting this, we have multiple ongoing initiatives that are designed to extend our manufacturing advantage by optimizing our manufacturing network and/or mitigating risks while continuing to ensure adequate supply of our products.

Amgen continuously invests in supply resilience

Amgen has a history of investing in our end-to-end supply chain to deliver on our mission to serve patients. We continuously evaluate our supply chain and invest to improve our resilience across five key elements:

- Infrastructure: Investments to ensure facilities can continuously operate by withstanding disruptive events such as earthquakes and hurricanes. This includes proactive supplier engagement to ensure they are investing to improve their infrastructure as well;

- Technology: Over the years we have also invested in advanced manufacturing technologies across our network. Our recent investments in digitalization and data analytics enabled us to leverage our central holistic monitoring system ('control tower') to gain end-to-end visibility 24 hours a day, 7 days a week and prevent supply disruptions;

- Inventory: We proactively manage our inventory levels from raw materials to finished products at various strategic locations, worldwide. In times of crisis, such as responding to the COVID-19 pandemic, we increase without delay our inventory levels for key raw materials and products according to the changing demand. This may support the supply of quality medication in the event of disruptions in a particular country or region that if a disaster strikes in one region, we can continue to provide quality medications to the market without disruption;

- Diversification: Along with inventory we have made strategic investments to our back-up manufacturing facilities to provide longer term operations should a disruption circumvent our Infrastructure or Inventory countermeasures;

- Business continuity: All our manufacturing sites have robust business continuity plans and continuously improve those plans through practice exercises. This safeguards Amgen's employees are trained and know what to do in the event of an unplanned event, while leveraging the other four investments outlined above.

We continuously review all these elements at least annually to evaluate, assess changes in both external and internal environments, and make necessary adjustments to retain our ability to ensure ‘Every Patient, Every Time.’

1Source: American Society of Health-System Pharmacists
Supply resilience in action: COVID 19 pandemic

- Consistent Supply: In the first five months of our COVID-19 response, we made nearly 300,000 commercial deliveries without missing a single patient. Automated monitoring systems were set up at multiple sites globally to collectively work around the clock actively managed to intervene, if needed, for 24/7 delivery, to secure direct-to-patient supply for commercial and investigational medicinal products;

- Agility: Decisions were made to increase the inventory of commercial and clinical products and the materials needed to manufacture them. 78 new transportation lanes were created, an increase of 17 percent from pre-COVID levels, to overcome uncertainties in freight capacity. The clinical supply chain was strengthened with inventory at warehouses, depots and clinics worldwide, and industry leading direct patient supply was set up in over 30 countries. And while we were assuring supply to current patients, we successfully launched more than 90 Stock Keeping Units (SKU) worldwide in the first half of 2020;

- Business performance: At the early stages of COVID-19, Amgen was among many companies to mandate social distancing. We enabled a large portion of our staff to communicate and collaborate with each other, our suppliers, and customers working from home. This helped reduce the number of people and risk our sites manufacturing medicines for our patients. At the same time, we increased our management cadence across manufacturing, quality, process development, and supply chain to ensure quick decisions as local disruptions were developing. As such, daily meetings and close attention to details became the immediate mode of operation;

- Risk Mitigation: Risk-based decisions were made and communicated timely to overcome challenges targeting resources and taking steps to ensure that manufacturing of products and respective supplies worldwide to fulfill demand as needed. Our Operations Data Strategy (ODS) became the critical success factor, transcending conventional processes, to enable faster decision making through visibility and smart analytics.

The changes in the way we work will make Amgen’s supply chain even stronger in a future beyond the COVID Pandemic, true to our mission of serving “Every Patient, Every Time.”

WEATHERING HURRICANE MARIA: WHEN OUR SUPPLY CHAIN WAS PUT TO THE TEST

Hurricane Maria—a devastating category 5 hurricane—hit Puerto Rico in September 2017. In its path was one of Amgen’s most important manufacturing facilities. Despite the historic storm, there were zero interruptions in supplying medication to patients around the world.

Every company plans for disasters and crises. For Amgen, that means a robust business continuity plan, consistent investments in infrastructure, and a mission-driven commitment from our staff.

In the case of Hurricane Maria, Amgen took proactive steps to ensure continued operations like moving to backup generators before the storm made landfall. Additionally, the dedication of our team in Puerto Rico—even in the face of their own personal adversity—was exceptional as they continued to show up every day to serve our patients.
AMN Healthcare Unites School Teletherapy with Interpretation Services to Reach All Students in Need

AMN Healthcare (NYSE: AMN) launched a unique service that combines teletherapy for schools with video interpretation services, allowing therapy professionals to communicate with any student, parent, or guardian who may be limited English proficient (LEP), Deaf or hard of hearing.

The new service combines an advanced teletherapy platform and the nation’s top school therapists, psychiatrists, social workers, and other care providers with medically qualified interpreters, enabling virtual patient-provider encounters in multiple languages including American Sign Language. Teletherapy helps school districts reach all students diagnosed with disabilities, including those needing interpreters, while also addressing the shortages of therapy professionals, particularly in rural areas and other underserved communities.

“The burden on school districts to provide consistent, quality therapy is higher today than ever before. Schools must overcome significant barriers to reach all the children who need help,” said Kelly Rakowski, Group President and Chief Operating Officer, Strategic Talent Solutions, at AMN Healthcare. “By combining teletherapy services with live interpretation from medically qualified interpreters, AMN Healthcare is expanding access to care and helping to improve health equity throughout the country.”

Growing in number over the last two decades, there are approximately 7 million disabled students in the United States, comprising 14 percent of national public school enrollment, according to data from the National Center for Education Statistics, which also shows that nearly 10 percent of all U.S. students are English Learners. Under the federal Individuals with Disabilities Education Act (IDEA), students with disabilities are guaranteed appropriate special education services.

The groundbreaking innovation combining school teletherapy with AMN Language Services represents the synergy of two pioneering companies recently acquired by AMN Healthcare.

School teletherapy provides speech language pathologists, physical therapists, occupational therapists, and school psychologists to schools throughout the country, including through a proprietary telehealth platform Televate®. AMN Language Services include the largest video remote interpreting service in the world with over 200 health systems, 2,200 hospitals, and thousands of clinics using its solutions.

AMN Healthcare Launches Return-to-Work Services for Organizations to Protect Employee Health

AMN Healthcare, the leader and innovator in healthcare total talent solutions across the nation, has launched a customizable, technology-enabled and clinically based service for businesses and other organizations to protect the health and safety of employees as they return to work.

As businesses welcome back employees and clients amid the coronavirus outbreak, they require effective solutions based on clinical protocols to ensure safety and confidence and to follow guidelines from state and local health departments. AMN return-to-work solutions provide a customized program for each employer along with all necessary staffing and protocols, which can include temperature checks, COVID-19 testing, onsite clinic support, quarantine management, and a telehealth platform.

These services are in use today by large employers across the globe and can be tailored to a variety of settings, including workplaces of all sizes, educational institutions, hospitality industries, entertainment venues, and others. They provide scalable options, based on evidence-tested clinical protocols, and include services that can be integrated into existing safety programs or comprehensive programs that meet an organization’s entire safety needs for reopening.

“It’s vital for all organizations to ensure the health and wellbeing of their employees as they come back to work,” Rakowski said.
As the leader in our industry, AMN Healthcare is well-known throughout healthcare for clinical and service quality, and now our expertise is helping industries safely reopen and resume business operations.

AMN operational expertise includes program planning and management to build and execute a customized program based on exact needs. AMN clinical expertise is supported by the nation’s largest network of pre-screened, qualified physicians, nurses, and allied health professionals. AMN also offers telehealth, virtual interpretation services, and other technology solutions that can be integral to an effective return-to-work program.

The nation’s most trusted healthcare partner is now helping businesses and organizations keep their team members safe as the economy reopens.

AMN Healthcare is the leader and innovator in total talent solutions for healthcare organizations across the nation. The Company provides access to the most comprehensive network of quality healthcare professionals through its innovative recruitment strategies and breadth of career opportunities.

With insights and expertise, AMN Healthcare helps providers optimize their workforce to successfully reduce complexity, increase efficiency and improve patient outcomes. AMN total talent solutions include managed services programs, clinical and interim healthcare leaders, temporary staffing, executive search solutions, vendor management systems, recruitment process outsourcing, predictive modeling, language interpretation services, revenue cycle solutions, credentialing and other services. Clients include acute-care hospitals, community health centers and clinics, physician practice groups, retail and urgent care centers, home health facilities, schools and many other healthcare settings.

AMN Healthcare is committed to fostering and maintaining a diverse team that reflects the communities we serve. Our commitment to the inclusion of many different backgrounds, experiences and perspectives enables our innovation and leadership in the healthcare services industry. For more information about AMN Healthcare, visit www.amnhealthcare.com

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Ascension’s Disaster Response Plans

About
Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As one of the leading non-profit and Catholic health systems in the U.S., Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2020, Ascension provided $2.4 billion in care of persons living in poverty and other community benefit programs.

Ascension includes more than 160,000 associates and 40,000 aligned providers. The national health system operates more than 2,600 sites of care — including 145 hospitals and more than 40 senior living facilities — in 19 states and the District of Columbia, while providing a variety of services, including clinical and network services, venture capital investing, investment management, biomedical engineering, facilities management, risk management, and contracting through Ascension’s own group purchasing organization.

Preparedness Efforts
Ascension uses a series of response algorithms to prepare for different disaster events (e.g. facility fire, thunderstorms, bomb threat, etc.). These condensed “tear sheets” allow for emergency leaders and staff to quickly respond to the disaster without having to look through more comprehensive materials. These tear sheets visualize response plans, ensuring that leaders can easily follow necessary steps to take.

96 Hour Plan
Ascension is always ready to respond to disaster events at quick notice. Hospitals have 96-hour plan templates to determine their readiness for a disaster on a 4-hour basis through 96 hours. These templates examine readiness across important areas, such as ensuring a stable water supply, maintaining uninterrupted communications with relevant parties and ensuring hospital facilities are secured. This allows hospitals to visualize their readiness throughout the duration of a disaster event and take necessary steps to ensure readiness.

Risk Identification and Site Criticality (RISC) Toolkit
Ascension uses the Risk Identification and Site Criticality (RISC) Toolkit developed by the Department of Health and Human Services (HHS) to create an objective, data-driven model for identifying risk in the healthcare space. The RISC Toolkit involves extensive collaboration between internal departments such as risk management, security, finance/insurance and facilities management, as well as partnerships with local, state and federal entities.

Each individual facility inputs data into the RISC Toolkit and will receive a rating for potential risk threats. This data metric can be used with Ascension’s other readiness plans to prepare for risks and ensure individual facilities have appropriate steps in place.

Disaster Preparedness Credentials
In order for facilities to respond to changing events, Ascension has implemented steps to allow practitioners to operate on a temporary basis in facilities to prevent shortages of care. These steps ensure that any practitioners granted such waivers are credentialed professionals who are held to the highest standards. These flexibilities allow for facilities to quickly meet staffing challenges so that there is no interruption of care, while ensuring these temporary practitioners deliver quality care.

#1 General Response to Smoke or Fire

**You see smoke or fire.**

- **R** Rescue anyone in immediate danger.
- **A** Call XXX. Pull Fire Alarm.
- **C** Close doors and windows to contain the fire.
- **E** Extinguish the fire with a fire extinguisher if safe to do so.

Tell the Operator:
- Your name
- Telephone number you are calling from
- Location of fire
- Extent of fire
- Type of fire (electrical, wastebasket)
- Your Emergency Assembly Point
- Calmly give complete information

**GENERAL RESPONSE TO SMOKE OR FIRE**
A Global Response to Hurricane Maria

Hurricane Maria hit Puerto Rico with devastating effects on September 20, 2017. Baxter activated a global response to the hurricane to support the needs of patients and healthcare providers in the U.S. and our employees on the island.

Thanks to the implementation of Baxter’s hurricane preparedness plans and the heroic efforts of our employees on the island, limited manufacturing operations resumed within a week of the storm’s passing. And full manufacturing production ramped up following the connection of all our facilities to the island’s electric grid in late 2017, which led to the resumption of pre-hurricane manufacturing levels in early 2018. All of the products made on the island are fully available.

Reliable and stable electric power was key to the full recovery of sustainable manufacturing operations on the island. Baxter maintained backup diesel generators in all facilities on the island to run the facilities during the grid power interruptions that occurred in the weeks and months following the hurricane, and continues to do so.

Baxter deeply appreciates the support of the Departments of Health and Human Services and Homeland Security, the Food and Drug Administration (FDA), the Federal Emergency Management Agency (FEMA), Puerto Rico Power Authority (PREPA), and Puerto Rico Governor Ricardo Rosselló and his staff for their support during our recovery.

A Global Response to Support U.S. Product Supply

In addition to the availability of SVPs, Baxter’s large-volume parenterals (LVPs, often referred to as “saline”) are fully available to customers across the U.S. Baxter does not manufacture LVPs in Puerto Rico, and Hurricane Maria did not interrupt their production. In addition, Baxter provided additional LVP units to support customer demand from a manufacturing facility in Mexico, through a permanent FDA approval.

Preparing for the Future: A Global Approach for Product Supply

To create additional manufacturing flexibility to support future IV solution needs in the U.S., Baxter worked with the FDA regarding permanent approval of several global facilities as alternate manufacturing sites, which would allow Baxter to import certain products into the U.S. The FDA has granted permanent approval for the importation of certain SVP and LVP products from facilities in Ireland, Spain and Mexico.

Supporting Baxter Employees and Communities in Puerto Rico

Baxter mobilized quickly in the aftermath of the storm to help our employees and their communities. Our work force not only faced daily challenges getting to and from work as transportation and services were damaged or destroyed, but they had to deal with the urgent basic needs of their own families and neighbors.

Baxter helped more than 2,000 employees in Puerto Rico procure necessities such as gasoline, food, water and toiletries. We coordinated multiple daily flights to transport approximately 25,000 pounds of needed supplies for employees. We distributed gas-powered generators and propane cooktops, and installed laundry stations at our manufacturing facilities to support employees’ personal needs. And Baxter provided employees with financial assistance to support their recovery.

In Puerto Rico, Baxter manufactures MINI-BAG and MINI-BAG Plus (small-volume parenterals, or SVPs) Container Systems, which are primarily used in the pharmacy to compound or admix a medication or to aid in the delivery of a medication, as well as amino acids and certain pre-mixed products.

To help support product supply for the U.S. market, Baxter activated targeted recovery strategies across our global manufacturing network, including working with the FDA to secure regulatory discretion for the temporary special importation of certain products from Baxter facilities in Ireland, Australia, Canada, Mexico, England, Italy and Brazil. Since the special importations began in October 2017, millions of units have been shipped to hospitals across the U.S.
Overview/Background

The Business Resiliency Services (BRS) Program is designed to maximize BlueCross BlueShield of Tennessee’s (BCBST) resilience in the event of a disaster or significant business interruption. The program seeks to:

- Protect the well-being of associates, contractors, contingency workers and visitors;
- Protect BCBST’s business processes, data, information and facilities;
- Ensure timeliness, availability and usability of business processes;
- Protect against potential threats (man-made or natural).

Description of the Program

The BRS Program, formally known as the Business Continuity and Disaster Recovery (DR) Management program, directs the day-to-day operational management of our business continuity and recovery capabilities. Major program activities include, but are not limited to, conducting an annual disaster recovery exercise, annual Business Impact Analysis (BIA), as well as bi-annual reviews of all business continuity and information technology (IT) disaster recovery plans.

The BCBST Information Services (IS) DR Methodology employs replication and backup technology, as well as a partial tape-based disaster recovery solution. We partner with multiple sources and leading disaster recovery organizations to conduct our annual DR exercise. The primary methodology for this exercise involves replicating and recovering data from our computer applications and systems identified in the annual BIA as business critical. As printing services are paramount to our business continuity, we include this service in this exercise, as well. Multiple participants from across the enterprise are engaged to recover, test and validate these systems and applications. In support of our program, special data and telecommunication circuits link to our DR site at a Chattanooga-based location some 10 miles from our primary office location to serve as our alternate office work site.

With the advent of data replication capabilities, BCBST has eliminated the previous extended and costly disaster recovery process that recovered data from tape. Data replication allows us to meet our contractual obligations and, as we continue to refine our processes, we improve our recovery times and volumes with each exercise.

BCBST conducts an annual BIA to revalidate business functions and recovery time objectives (RTOs). BIA Contributors review their respective business functions to update applications, resources, vendors, and other supporting business functions, as well as to provide answers to additional business impact-related questions. The annual review uses multiple tools, including business continuity software.

Our BRS team engages BIA Contributors bi-annually to gain more insight into business function dependencies and impacts. A BIA Contributor updates the business function information in the business continuity software and then submits the function for management approval. This ensures the information is current and logged accurately in the DR software.

Update Coordinators are assigned to review and update their respective Business Continuity Plans (BCP) every six months and receive system-generated notifications when the reviews are due. The Update Coordinators are responsible for ensuring the business function dependencies (e.g. applications, vendors, resources), teams and recovery procedures specific to the plan are current. Workarounds are included in these plans in the event of technology outages. Prior to employing business continuity software, BCPs were reviewed and updated by the BRS team. Now, designated Update Coordinators conduct the reviews, allowing for appropriate accountability and improved plan accuracy.

Since 2016, all BCPs and IT DR application plans are reviewed annually via tabletop exercises. The tabletop exercises consist of a “disaster” scenario presented to plan participants. Before 2016, the BRS team worked to exercise only core plans individually. The scope widened over time to include larger, more integrated efforts where two or more plans were exercised at the same time. ITDR application plans are also tested during the annual disaster recovery exercise.
In conjunction with the above disaster recovery and business continuity activities, the BCBST BRS team is responsible for maintaining and exercising crisis management team plans, which include our pandemic response plan. As a result of the recent COVID-19 outbreak, our pandemic response has been instrumental in delivering the extremely robust work-from-home capabilities that have allowed our employees to work successfully and stay safe at home since March 2020.

**Metrics/Results/Value**

BCBST’s BRS Program has evolved over the years and now provides the platform on which our ability to remain resilient and recover during a crisis relies. The key component that makes this program successful is our dedication to practicing our plans and refining the processes with each test. With this diligent practice, we have reduced our recovery time for core systems and applications by over 50 percent. Within the last four years, we have increased the number of applications recovered by nearly 100 percent and the number of servers by 80 percent. With each yearly data center exercise, we discover ways to improve the program and further reduce our recovery point objectives over time.

When it comes to disaster recovery and business continuity planning, nothing is 100 percent foolproof. And, as eloquently stated by Desmond Tutu, there is no "quick fix" – “just like eating an elephant, it requires one bite at a time.” The proven way to enhance resiliency and recovery capabilities is to practice, practice, practice. With continual practice, optimum results can be achieved over time.
COVID-19: Preparing for the Fall

COVID-19 Testing Industry Consortium

The COVID-19 pandemic has continued to drive an unprecedented and increasing demand for diagnostic testing. The coming months are shaping up to be potentially challenging to the health care system as the desire to sustain reopened schools and businesses collides with the respiratory virus and influenza season alongside a resurgence in COVID-19 cases.

While testing is a critical component involved in minimizing transmission, it’s not the only factor. Other public health initiatives are critical, including social distancing, masking, etc., which can, and have, had a dramatic impact on spread of disease. And yet, as we learn about asymptomatic and pre-symptomatic patients’ ability to infect and the potential for long-term deleterious effects of this disease, it remains evident that there is a need for more frequent and accessible screening for asymptomatic individuals and testing for diagnostic purposes to prevent transmission and manage the disease.

The United States increased testing capacity for COVID-19 from near zero in early March 2020 to approximately 1 million tests by fall 2020 (Figure 1). As a country and as an industry, we need to increase testing capacity and “widen the road.” Governments play a key role in all aspects of testing, including facilitating fast approvals of good tests and providing labs financial incentives to expand quickly.

A coordinated response will continue to increase capacity and access the resources necessary to get results back in less than 48 hours; while simultaneously expanding viral targets within COVID-19 tests to include seasonal respiratory viruses such as influenza and respiratory syncytial virus (RSV), diseases that have symptoms similar to COVID-19, we prepare for the upsurge.

Laboratory capacity constraints may be further exacerbated as individuals who chose to defer testing for other diseases during the upsurge of the pandemic are no longer able to postpone testing. In cases of cancer, laboratories saw a testing decrease of 15-25 percent over three months.

Figure 1. Number of COVID-19 tests per day in the US
We propose a series of recommendations to help our nation meet this unprecedented testing need through the integration of testing strategies and tactics into other policy considerations.

Sample Pooling
Laboratories can significantly increase testing capacity through the use of sample “pooling.” Patient sample pooling, the process by which multiple patient samples are combined before testing, is commonly viewed by diagnostic experts as the most viable and straight forward path to increasing testing capacity from our current state. However, this approach only makes sense from an economical and testing capacity perspective if 1) the positivity rate is below a certain threshold, and 2) the pooling size is not too large (i.e., four-sample pooling leads to a four-fold increase in limit of detection). Limit of detection, or LOD, is a measure of how many copies of virus must be present in a sample for a test to report a positive result. It has been estimated that every ten-fold increase in test LOD, leads to a 13 percent increase in false negative rate. Provided the sensitivity of the assay is sufficient and the prevalence of positive patients is sufficiently low enough, pooling presents a viable mechanism for reducing the burden on the testing system.

Sampling
There is also a tremendous burden on our front-line clinical workers, many of whom are stretched beyond reasonable limits. We will also need to improve how we prioritize the deployment of our clinicians and resources. We can reduce the demand on clinicians, while concurrently minimizing the risk of health care worker exposure through the utilization of alternate self-collection devices (e.g., saliva, nasal swab), which are consumer-friendly, pain-free alternatives to replace previously used collections, which some refer to affectionately as “brain scratching.” We believe that the discomfort and fear associated with initial sampling approaches for testing have reduced the willingness of individuals to get tested.

This diversification of collection approaches will go a long way toward alleviating critical supply-chain demands for testing resources, and “fit for purpose” deployment of these capabilities should be assessed.

Ensuring High Quality Testing Through a Lab Proficiency Program
Review of the emergency use authorizations (EUA) filings with the FDA for protein antigen and polymerase chain reaction (PCR) tests shows that almost all systems report similar positive and negative agreement values above 95 percent. However, we know that false negatives and false positives are significant concerns in testing today, despite the reported high sensitivity and specificity. An alternative approach is needed to ensure confidence in the quality of COVID testing results.

Traditionally in the laboratory testing industry, testing proficiency programs administered by a central government agency like the Centers for Medicare and Medicaid Services (CMS) are used to ensure high quality test results. Proficiency programs consist of CMS sending blinded samples to clinical laboratories to demonstrate performance. We recommend that a similar proficiency approach be implemented for SARS-CoV-2 for both laboratories and providers of point-of-care devices — so that a minimum quality standard can be established, along with a true estimation of test sensitivity and specificity.

Centralized Sample Routing, Reporting, and Contact Tracing
A centralized, national system for results reporting, sample routing and contract tracing is a must. Laboratories are currently required to report at both state and local levels. With 50 states and 3,141 counties, many with differing requirements, the burden is too great and costly.

The nation is not currently fully maximizing existing laboratory capacity. Often, some laboratories have sample testing backlogs while others sit idle. A centralized system for routing samples to laboratories with excess capacity and shorter turnaround times could help alleviate “sample traffic jams.”

Prescriptions could be eliminated and instead the centralized system for results reporting and sample routing could also be used for patient follow-up and contact tracing. There is little to no difference in viral load and likely associated transmissibility in pre-symptomatic, asymptomatic or symptomatic patients, thus reducing viral spread can’t just be limited to just symptomatic patients diagnosed by a physician. Pre-symptomatic transmission is likely occurring in approximately half the cases. Eliminating prescriptions would promote broader access and help control virus spread.

Promoting New Test Development and Increased Laboratory Testing Capacity
The creation of a centralized sample repository, administered by the FDA or CDC, would accelerate new test development. This repository should include SARS-CoV-2, influenza, and RSV specimens in a variety of different collection media to support the creation of robust tests to diagnose these similar-symptom diseases, either as stand-alone tests or in combination.
Finally, we need to find unique ways to support additional investment in people, systems and reagents across the testing landscape; traditional “research funding” may not be the most effective mechanism. Existing laboratories and diagnostic companies must be encouraged to make capital investments and rapidly expand their capacity to respond to pandemics such as COVID-19. One suggestion would be to create government-backed, upfront, low-interest, forgivable loans tied to achievements in increased testing capacity. For example, CLIA laboratories or diagnostic companies could be eligible for loans equal to 25 percent of their quarterly projected COVID volume increase. A laboratory that agrees to expand its capacity or test production by 100,000 tests per quarter would be eligible for a $2.5 million loan (100,000 x $100 per test x 0.25 = $2,500,000) at a 1 percent interest rate. All or a portion of the loan could be forgiven based upon the increase in testing volume that is achieved. Another incentive would be a government program that pre-purchases diagnostic tests, which could fund research and expansion in subsequent periods.

Conclusions
There is no single “magic bullet” to address the complexities of a pandemic like COVID-19. Scientific knowledge of the disease unfolds daily. The uniqueness of our nation’s healthcare and political structures bear a diversity that is not dissimilar to country-to-country differences in other parts of the globe. We advocate the need for a more centralized, broader, holistic approach that extends from science to public policy.

In summary, our shared recommendations include:

1. Implementation of a more diverse sampling approach which includes nasal swabs, saliva, etc., in addition to nasopharyngeal swabs, both with centralized collection as well as self-collected sample specimens and pooling, where appropriate.

2. Development of a nationally administered proficiency and quality program to evaluate real-world test performance and set minimum performance requirements.

3. Creation of a centralized system for results reporting, sample routing and contact tracing.

4. Elimination of prescription requirements for COVID-19 testing in all jurisdictions.

REFERENCES
Achieve Effortless Interoperability With Change Healthcare APIs

The Rising Demand for Telehealth

After COVID-19 hit the United States, telehealth utilization skyrocketed, hitting its peak in March 2020 before beginning a slow decline by mid-May. Analysis of Change Healthcare’s 2020 claims data reveals that outlays for telehealth services exploded from less than $2 million to almost $140 million in a span of six weeks. The pandemic has already introduced thousands of Americans to the safety and convenience of online care interactions—and the demand is only expected to grow. According to national consumer research conducted by the Harris Poll and commissioned by Change Healthcare, 65 percent of consumers plan to use telehealth services more often than they did before the pandemic. A full 78 percent of consumers report that COVID-19 has revealed how much the healthcare system needs more digital and telehealth options.

Enabling a Virtual Care Experience

For providers and telehealth vendors, of course, the behind-the-scenes challenges involved in the execution of digital care visits are the same as for in-person appointments.

In addition to the actual encounter, healthcare organizations must also virtually engage with patients both before and after the visit. They need to be able to:

- Help patients find a care provider and schedule an appointment;
- Check eligibility and determine out-of-pocket costs;
- Prepare for the visit by knowing the patient’s history;
- Order lab tests and prescriptions;
- Submit a claim;
- Ensure post-visit payment;
- Manage at-home care.

Creating the Virtual Experience

With intelligent integrations application programming interfaces, or APIs, are the intelligent integrations that enable all of this functionality at scale. APIs connect disparate systems to enable seamless data sharing and communication.

That’s key to keeping pace in the digital era: 84 percent of businesses say API integration is critical or somewhat critical to their success.
Introducing Change Healthcare APIs

Change Healthcare’s APIs allow telehealth innovators to easily leverage the power of our networks and capabilities to integrate common healthcare workflows into their applications.

Our open, standards-based API products are more than simply code. They include access to data, networks, and the embedded functionality that powers Change Healthcare’s industry-leading financial, clinical, and engagement solutions.

Our APIs Create Unified patient and Provider Experiences

Our Telehealth Medical Eligibility and Claims Management bundle is designed to help telehealth vendors address the specific challenges virtual care poses. It streamlines the patient intake process with APIs for eligibility checking, claims submission and status, as well as responses and reporting. This bundle of valuable APIs is powered by AWS.

Our Telehealth Lab Orders, Results and ePrescribe bundle addresses connectivity challenges telehealth vendors face when attempting to order lab tests and prescribe medications. These APIs let users leverage our extensive network to streamline electronic order generation and results delivery, and connect to our network of labs, pharmacies, and radiology sites.

Our API Products Help Accomplish Goals

By using Change Healthcare’s API products, developers can focus on building:

- The best front-end interface to engage and interact with end users;
- Innovative workflows to optimize back-end transactions;
- Interoperability across disparate healthcare systems.

Our Commitment to Our Clients

Our API products are built to common standards to promote security, interoperability and scalability. To ease adoption and use, we provide comprehensive enablement tools including documentation, implementation guides, and a sandbox.

Access Our API Products Online

Change Healthcare’s API & Services Connection™ Marketplace provides a vast array of APIs to help payers, providers, partners, consultants, vendors, and independent developers:

- Create innovative new solutions
- Improve or enhance existing solutions
- Accelerate implementation or speed to market
- Save significant time and expense

Products in the API & Services Connection Marketplace reflect the breadth of our industry-leading solution portfolio, which includes:

- Coverage and eligibility;
- Workflow optimization and patient and member engagement;
- Data interoperability;
- Claims and billing payment and reimbursement;
- Care operations and management.

Change Healthcare is a leading independent healthcare technology company that provides data and analytics-driven solutions to improve clinical, financial and patient engagement outcomes in the U.S. healthcare system. We are a key catalyst of a value-based healthcare system, accelerating the journey toward improved lives and healthier communities.

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1 According to Change Healthcare’s 2020 Benchmark claims dataset representing 3.4 billion claim lines.
2 Ibid.
4 Ibid.
Vaccination Credential Initiative

A broad coalition of health and technology leaders have announced the creation of the Vaccination Credential Initiative (VCI), committed to empowering individuals with digital access to their vaccination records based on open, interoperable standards.

The current vaccination record system does not readily support convenient access, control and sharing of verifiable vaccination records.

VCI coalition members are working to enable digital access to vaccination records using the open, interoperable SMART Health Cards specification, based on W3C Verifiable Credential and HL7 FHIR standards.

VCI’s vision is to empower individuals to obtain an encrypted digital copy of their immunization credentials to store in a digital wallet of their choice. Those without smartphones could receive paper printed with QR codes containing W3C verifiable credentials.

“The goal of the Vaccination Credential Initiative is to empower individuals with digital access to their vaccination records so they can use tools like CommonPass to safely return to travel, work, school and life, while protecting their data privacy,” said Paul Meyer, CEO of The Commons Project Foundation. “Open standards and interoperability are at the heart of VCI’s efforts and we look forward to supporting the World Health Organization and other global stakeholders in implementing and scaling open global standards for health data interoperability.”

“As we explore the many use cases for the vaccination credential, we are working to ensure that underserved populations have access to this verification,” said Dr. Brian Anderson, chief digital health physician at MITRE. “Just as COVID-19 does not discriminate based on socio-economic status, we must ensure that convenient access to records crosses the digital divide. MITRE is an independent advisor and trusted source for managing third-party data and proud to be joining with The Commons Project and other coalition members to deliver an open-source credential.”

“A secure, convenient solution to verify COVID-19 vaccination will play an important role in accelerating a healthy and safe return to work, school and life in general,” said Joan Harvey, president of care solutions at Evernorth, Cigna’s health services business. “Evernorth is helping to lead this important work because the digital vaccine certification made possible by this collaboration will put people in charge of their own health data through innovative technology. It furthers our mission to tackle healthcare’s biggest challenges.”

“This process needs to be as easy as online banking. We are committed to working collectively with the technology and medical communities, as well as global governments, to ensure people will have secure access to this information where and when they need it.”

“Salesforce is proud to join the Vaccination Credential Initiative to help organizations easily and safely customize all aspects of the vaccination management lifecycle and integrate closely with other coalition members’ offerings, which will help us all get back to public life,” said Bill Patterson, executive vice president and general manager, CRM Applications at Salesforce. “With a single platform to help deliver safe and continuous operations and deepen trust with customers and employees, this coalition will be crucial to support public health and wellbeing.”

“The standards being developed by the Vaccination Credential Initiative, combined with availability of inexpensive smartphone-enabled rapid tests the FDA is now beginning to authorize for home use, will enable application developers to create privacy-preserving health status verification solutions that can be seamlessly integrated into existing ticketing workflows,” said Ken Mayer, founder and CEO of Safe Health. “SAFE is currently working with Hedera to develop a blockchain-enabled crowd safety solution using the VCI standards designed to help get concerts and sporting events going again.”

“Cerner is already providing tools to clinics, hospitals and other venues that provide health care to support the rapid COVID-19 vaccination process and ensure a safe, streamlined experience. This initiative will grow the standards around data exchange and help patients have access to and easily share verified vaccination information via their mobile device in situations where proof-of-vaccine is necessary,” said David Bradshaw, senior vice president of Consumer and Employer Solutions, Cerner. “Cerner is committed to continuing to be an industry advocate for standards-based access to health information.”

“We are kicking off the most significant vaccination effort in the history of the United States. Now more than ever, individuals need access to their own vaccination and health information in a portable format to begin to move about the country safely and comfortably,” said Ryan Howells, principal at Leavitt Partners and program manager of the CARIN Alliance. “The CARIN Alliance is supportive of MITRE’s effort to provide individuals with access to their vaccination information in a secure and trusted way and looks forward to advising the VCI initiative on ways to leverage the CARIN code of conduct and other best practices to facilitate consumer-directed exchange that we have developed consensus on over the last few years.”

See the Vaccination Credential Initiative website at vaccinationcredential.org for more information.
Cleveland Clinic’s COVID-19 Response

After the first COVID-19 case was identified in Ohio on March 9, 2020 Governor Mike DeWine declared a State of Emergency and issued executive orders to prevent its spread. Along with closing schools and non-essential businesses, the executive orders also prohibited non-essential medical care, including surgery, to preserve personnel protective equipment and save hospital beds and resources for the anticipated COVID surge.

Preparing for a Surge

Cleveland Clinic’s Enterprise Analytics adapted the University of Pennsylvania open-source tool to conduct initial modeling, which suggested that an unrestrained outbreak may lead to a maximum census of nearly 8,000 patients in our 21-county market. The executive team quickly mandated preparations for the worst-case scenario and made plans to triple our regular nursing floor and intensive care capacity. We significantly increased system capacity by converting the medical education campus into the Hope Hospital with over 1,000 additional patient beds.

Public-Private Partnership

In late March Governor DeWine invited a small group to meet with him in Columbus to talk about how the state should prepare for the pandemic and to give him some insight into the coronavirus. We suggested the state collapse its eight emergency regions into three more manageable zones (Cleveland, Columbus and Cincinnati) and appoint zone leaders to coordinate health care delivery between local health departments, medical care providers, and congregate living facilities. Dr. Robert Wyllie, Cleveland Clinic’s Chief of Medical Operations, was appointed the Zone 1 (Northern Ohio) lead on April 1. Located in Region 2 of Zone 1, Cleveland Clinic hospitals convened with University Hospitals and MetroHealth with a collective commitment to expand care delivery.

State facilities, including correctional facilities, house approximately 50,000 individuals, and Ohio’s nearly 900 privately-operated nursing facilities care for 70,000 residents and employ 80,000 individuals. In Zone 1 we linked each of the facilities with a medical provider and the local health department and then coordinated laboratory testing of all employees and symptomatic residents.

One of our first challenges in Zone 1 was the Elkton Federal Penitentiary in Columbiana County, which had several hundred COVID-positive inmates and guards. Those requiring hospitalization quickly overwhelmed the local hospitals in Salem and East Liverpool. We organized a cascading system of care to send patients to Akron then Cleveland to relieve the smaller hospitals. A similar situation occurred a few weeks later in the Veterans Home in Sandusky, Ohio. Just letting people know we are here to help seemed on several occasions to alleviate fear and help manage the outbreaks.

Cleveland Clinic and University Hospitals partnered in planning testing sites and management of post-acute facilities. Residents in congregate facilities from assisted living homes to skilled nursing facilities nationally account for 7 percent of the patients infected with COVID, but 40 percent of the fatalities. Both Cleveland Clinic and University Hospital trained swab teams to test employees and residents in congregate facilities while providing PPE and medical advice as needed.

COVID hospitalizations first peaked in Ohio on April 22 with 1,103 patients in the hospital, including 522 in the intensive care units and 357 on ventilators. With the state intervention the number of hospitalizations dropped to 512 on June 20, with 203 patients in the ICU and 131 on ventilators. As cases declined, the Governor ordered the gradual re-opening of the state on May 14.

The second hospitalization peak occurred on July 22 with 1,122 individuals hospitalized with COVID, occupying 348 intensive care beds and 174 ventilators. The resurgence lead the governor to institute a county COVID management policy, the Ohio Public Health Advisory System, that mandated a series of preventative steps designed to mitigate the spread of the disease. Ohio’s 88 counties were graded on a number of infection parameters that led to a classification as one of four levels (Yellow, Orange, Red and Purple). Initially 15 of Ohio’s 88 counties were at the level 3 (red), mandating citizens to limit activities as much as possible. Governor DeWine subsequently reinstated a mandatory mask rule resulting in a steady decline in COVID cases and hospitalizations.

The fall/winter peak that started in late September has resulted in the highest number of new cases and hospitalizations since the start of the pandemic.
The initial rise in hospitalizations started three weeks after the Labor Day weekend and corresponded with students going back to school. This third wave started in rural counties and had spread to urban centers, including Cuyahoga and Franklin Counties (Cleveland and Columbus respectively). As part of zone management, we have increased the number of zone calls and reviewed surge plans, including load balancing among hospitals, as the need might arise. The current challenge is not in PPE that was the case in the first peak but personnel since a majority of counties attained level 3 or 4 public emergencies at some point during the fall-winter surge.

Clinic Enterprise Analytics modeled our 21-county referral area and provided material through the zone leadership and Ohio Hospital Association (OHA) for the entire state. Cleveland Clinic and University Hospital combined their data and used geo-spatial analytics to recognize micro-clusters of COVID positive patients. Together we have developed an early warning system that has been demonstrated to the State of Ohio. The Governor has requested we proceed with the Ohio Hospital Association and develop a statewide system that would alert local county and city departments of health and educational institutions about potential outbreaks.

Cleveland Clinic has experienced success with its home monitoring program to stay connected with patients our system has identified as having COVID-19.

Remote Monitoring

Cleveland Clinic has succeeded with its home monitoring program to stay connected with patients our system has identified as having COVID-19. Remote monitoring allows beds to remain open to the sickest patients. The home monitoring team connects daily with enrolled patients on a daily basis to ensure they are doing well and isolating appropriately. Using smart phone technology, patients can log their symptoms; physicians are available on virtual standby to intervene when patient symptoms worsen. By November 2020, more than 7,200 COVID-positive patients have enrolled in the program.

Because Cleveland Clinic does the majority of testing in our region, the patients enrolled in this program represent almost half of the cases in Cuyahoga County.

Treatment

Treatment evolved over time with less intubation and more use of high flow oxygen and “proning” (i.e., placing patients on their stomachs to facilitate breathing). In addition, two medications became available — remdisivir and dexamethasone — for treatment of COVID patients. The mortality rate dropped in our oldest most vulnerable populations (those 65 and older that account for nearly 80% of the fatalities).

Remdisivir became available in mid-May under an emergency use authorization declaration and was shown to shorten the duration of hospitalization but did not influence mortality. It was distributed along the three zones initially with the hospitals with the highest number of ventilated patients and later the total number of COVID hospitalizations. The state allocations were not fully utilized so all hospitals that requested medication were able to obtain the drug. Dexamethasone was shown to benefit ventilated patients later in the course of the disease and reduce the frequency of lung complications.

Vaccines

Zone leadership with OHA has helped the State to coordinate vaccine distribution and administration. Four vaccines were in phase three clinical trials in the U.S. by late 2020. The U.S. Department of Health and Human Services has indicated 100 million doses should be available in January. The priorities suggested by HHS include the most vulnerable populations in the congregate settings, as well as health care and other essential workers. The Pfizer vaccine needs to be stored at minus 70°C and the Moderna vaccine at minus 20°C. Freezers to meet these requirements were in limited supply. We have collected an inventory of the available refrigeration units around the state. The RNA vaccines require two injections separated by 28 days for the Pfizer vaccine and 21 days for Moderna’s.

1 CCF ICU COVID-19 Outcomes Summary (based on discharges on or before August 31, 2020):

- Average APACHE III Score: 59.29
- ICU survival: 82%
- Hospital survival: 78%
- ICU survival of invasive mechanical ventilation (IPPV): 69%
  - ≥ 65 years old: 56%
  - <65 years old: 85%
- Age-stratified Hospital survival
  - ≥ 65 years old: 69%
  - <65 years old: 90%

- Race/Ethnic Origin Hospital survival
  - White/Caucasian: 75%
  - Black/African/Haitian: 81%
- Gender Hospital survival
  - Male: 79%
  - Female: 77%
- Average ICU LOS: 6.67
- Average hospital LOS: 12.42
- Average duration of MV: 10.12

25 | Disaster Preparedness and Response | A compendium of best practices from the healthcare industry
Introduction

While most disasters or critical events are unpredictable, some are both routine and come with forewarning. It is these events that give the most opportunity to prepare and respond in a uniform manner. Being well practiced in these events provides a template and training for responding to and in events that are unpredictable — whether they are global pandemics, active attackers or anything in between. One critical event that is both routine and comes with warning is a hurricane.

Cotiviti uses hurricane season to examine, refine and utilize its emergency response plans. While some of these steps are not utilized in unplanned emergencies, the fundamental structures are applicable in a wide variety of circumstances.

Identification of Event

Hurricanes generally come with substantial notice. The Cotiviti Corporate Security team is responsible for identifying and tracking hurricanes to assess their potential impact on Cotiviti employees and business operations. The Cotiviti Corporate Security Team utilizes the National Hurricane Center’s predictive models to track storms. Once a storm (hurricane or tropical storm) shows likely impact on the United States within the next 48 hours (in the event of a high-quality forecast of a significant strength storm, the Corporate Security Team will initiate the next process as soon as reasonably possible), the Corporate Security Team:

1. Identifies likely impact area based on the National Hurricane Center “cone of uncertainty” forecast.
2. Utilizing our emergency communications platform, communicates via text and email to all employees who reside within any possible impact areas:
   a. That we are tracking the storm;
   b. That they should ensure they follow all guidance from local authorities;
   c. That they should inform their manager, HR or Corporate Security of any planned evacuations;
   d. That follow-up communications will come to assess their well-being prior to, during, and after the storm.

The Corporate Security Team then provides a list of the employees who have received this communication to Human Resources. In a smaller event, Human Resources personnel reach out to managers and potentially impacted employees directly to reiterate this message. In a larger event, Corporate Security and Human Resources will collaboratively communicate with business unit leaders to assess potential wide-scale impact to productivity.

The list of affected employees is continuously refined as forecast quality improves over time.

Prior to Event

High quality and vetted pre-work is critical to ensuring appropriate response. Cotiviti has established an information feed from its human resources database to its emergency communications platform. The information exchanged includes employee’s contact information (both work and personal) and physical addresses. This information is uploaded weekly to ensure it is up to date in scope and detail.

The other key piece of pre-work is routine confirmation of roles and responsibilities with all key participants.
Should any employees be required to evacuate, the company may elect to provide for additional resources (hotel rooms, office space) to assist impacted employees. The need for additional assistance is assessed on a storm by storm basis.

During the Event
During the event, a “quiet period” is generally implemented. This intentional limit on communication to affected employees is to ensure that their limited communication resources (cell phone batteries, strained infrastructure) are preserved for critical life-safety use.

Utilizing National Hurricane Center information, contracted intelligence providers and public reporting, Corporate Security reassesses the original communication list, identifying the employees likely to be most heavily affected and provides this list to Human Resources for triage as soon as reasonable.

Concluding the Event
As the storm passes, Corporate Security issues “check in” communications with all potentially impacted employees as Human Resources reaches out to those identified as likely needing additional assistance. Human Resources and Corporate Security partner in the event of any employee needing significant support (such as those who may have lost a primary residence).

Results from Previous Events
During the 2020 hurricane season, the described process was utilized for seven distinct events with over 400 distinct communications sent. While this is successful in and of itself, it also was critical validation of the quality of both the process and the communication tools. Should these processes or tools be needed in a critical event, this validation ensures their capabilities.
Epic: Lessons Learned Supporting COVID-19 Data Sharing and Public Health Reporting

Secure, standards-based data exchange has helped health systems and public health organizations across the country collaborate to respond to COVID-19, particularly by managing hospital capacity, coordinating testing, and sharing data to inform public health policies and re-opening strategies. Expanding standards for health information exchange, developing thoughtful data definitions, and investing further in public health infrastructure will help the country prepare to widely distribute the COVID-19 vaccine and respond to future pandemics.

Accelerating Data Sharing to Inform Public Health

Health systems using Epic promptly began submitting important information about COVID-19 cases to public health agencies using existing health information exchange standards. Epic’s comprehensive support for established reporting standards and data transmission mechanisms helped Epic aggregate COVID-19 relevant information from health systems for large-scale reporting. For example:

- Electronic case reporting, lab reporting, and immunization reporting to public health agencies, which saved crucial time, were easier and faster for health systems to do because they had already set up connections for data exchange. These established standard connections created a ready-to-use framework for critical COVID information exchange between health systems, labs, and public health agencies.

- Within a few weeks of the public health emergency declaration, public health agencies across the country could access Epic’s near real-time analytics platform, Pulse Central, to view aggregated COVID-19 relevant data from more than 1,000 hospitals using Epic. This data was summarized on a central dashboard to depict the impact of COVID-19 county-by-county through testing rates, hospital capacity, and other metrics. The data in Pulse Central data was aggregated and shared with permission from health systems and is updated automatically to help avoid burdensome manual data entry.

Using the Integrated Health Record to Respond to Testing Needs and COVID-19 Surges

Integrated electronic health record software and an existing framework for quickly sharing health information and best practices helped health systems using Epic quickly expand their testing efforts, effectively communicate with staff and patients, and increase capacity for treating COVID-19 patients. For example:

- Health systems set up variations of a patient-centric testing workflow to conduct thousands of COVID tests in different settings, from mobile units to drive-up testing. After tests were ordered and resulted, Epic’s software helped care coordinators use a single, patient-centric model to provide follow up care and attention, and remotely manage care when appropriate.

- At temporary surge sites across the country totaling more than 92,000 beds, including New York’s Javits Center, physicians and nurses had access to patients’ full medical records sent via the secure Care Everywhere exchange framework. These experiences were also put to use in October to set up an emergency care facility at Wisconsin’s state fairgrounds and in the USS Comfort. Epic provided hands-on support for system configuration, training, and advice for these surge sites at no cost.

- Best practices based on hundreds of EHR implementations and health systems’ COVID-19 experiences were shared with health systems across the country to inform the intake and management of COVID-19 patients. For example, clinicians at Lee Health in Florida used Epic to quickly identify a connection between COVID-19 and blood clots, while Parkview in Indiana enhanced Epic’s deterioration predictive model to better monitor COVID-19 patients specifically. These insights were made possible by an integrated EHR and quickly shared across a broad community of health systems.
Standardizing Data Definitions for Future Epidemic Preparedness

To respond effectively to future public health emergencies, public health authorities and healthcare organizations must work together to standardize data definitions for relevant data. The COVID-19 pandemic highlighted many important lessons regarding the importance of standard data definitions. For example:

- Some information that public health agencies requested to inform their response to the pandemic is not standardly represented within electronic health record software, such as discrete data for personal protective equipment (PPE) supplies in a hospital or across a region, which might instead be stored in an enterprise resource planning system. For example, there is not a current standard for how a ventilator is defined or how to determine from EHR data whether it’s in use, making reporting difficult. Collaboration between private sector experts and the government can help identify the necessary data and how best to capture and share it before a crisis occurs.

- Shared data definitions foster shared understanding. These serve as an important resource for disparate health systems and regions working together to understand COVID-19. Local, state, and federal agencies are best prepared to respond to a crisis when their reporting requirements are grounded in shared data definitions, and their decisions are based on this shared understanding of how to interpret the data. We worked with HL7 to propose a new standard for sharing aggregate data to support responses to epidemics that we suggest should be adopted industry-wide.

- Standards-based data is used by health systems, to determine the need for a surge facility; by regions, to determine the area’s ability to respond to additional hospitalizations; and by states, to evaluate the overall impact of COVID-19 in a given week. Sudden changes to data capture and reporting requirements from the federal government have wide-ranging effects on healthcare organizations and local public health agencies and must be done in collaboration with healthcare provider organizations and their health IT systems.

Additional Information

Helpful Resources

- To learn more about health systems’ responses to the COVID-19 pandemic, refer to the following overviews on Epic’s website:
  - Eliminating Manual Transcription of COVID-19 Lab Results Cuts Wait Time in Half
  - Public Health Agencies Connect with the Epic Community to Track COVID-19 with Pulse Central
  - Epic AI Helps Clinicians Predict When COVID-19 Patients Might Need Intensive Care
  - Identifying and Addressing Inequities Intensified by COVID-19
  - How to Get a Hospital Expansion or Surge (Alternate Care) Facility Ready for Patients with COVID-19

- For insights about the pandemic based on our data scientists’ and physicians’ analysis of EHR data, including observations about a drop in preventive care during the pandemic or patients’ outcomes on ventilators, refer to the Epic Health Research Network

Contacts

- For more information about lessons learned from setting up surge facilities and expanding testing access nationwide, contact Nick Frenzer at nfrenzer@epic.com.

- For more information about public health reporting data standards, contact Paul Sobanski at psobanski@epic.com.

- To learn more about data sharing with public health agencies using Epic’s Pulse Central, contact Phil Lindemann at Phil@epic.com.

- To learn how health systems using Epic automated COVID-19 case reporting to public health agencies, contact John Stamm at jstamm@epic.com.
HMS/NDHI Recommendations

Care Delivery

Enabling Telehealth/Virtual Care
Telehealth is a vital tool during emergency situations as seen in the COVID crisis. The following recommendations will improve access to telehealth, while concurrently ensuring its proper use.

1. Provide consumer education on telehealth benefits. A J.D. Power study conducted between March 15 and May 1, 2020 found that 75 percent of consumers are aware of telehealth, but 54 percent do not know if their insurer covers such benefits. Expanding the scope of telehealth importantly includes concerted patient education and outreach regarding their benefits for and instructions on how to use telehealth benefits.

2. Ensure proper payment of telehealth services. Telehealth is highly vulnerable to improper payments and fraud, waste and abuse. Institute a thoughtful pre- and post-payment review that does not impede access, yet ensures care was rendered, is in accordance with nationally recognized practice standards, and is billed and paid appropriately.

Maintain & Adapt Patient Outreach and Engagement
During an emergency, it’s imperative to stay connected with healthcare consumers, providing information relevant to the crisis at hand and their health and well-being.

1. Assess validity and timeliness of “routine communications.”
2. Provide timely information on the crisis at hand. Examples from the COVID crisis include providing information on how to stay safe, access telehealth and/or other new benefits, when and how to get tested and vaccinated for COVID.

3. Maintain “routine communications” with at-risk, chronically ill populations to ensure continued access to care, thereby mitigating against declines in health status.

4. Permanently remove regulatory barriers to patient engagement. The Telephone Consumer Privacy Act of 1991 (TCPA) was originally intended to stop the scourge of telemarketing calls and uninvited solicitations, but TCPA blocks many beneficial healthcare communications. Changes are needed to TCPA allowing for patient engagement generally, and specifically during national and local disasters not dependent or contingent on a Federal Communications Commission declaration.

5. When enabled and used correctly, patient outreach has yielded positive outcomes, including:
   a. 53 percent increase in cervical cancer screening rates;
   b. 45 percent increase in mammograms;
   c. 30 percent increase in childhood immunizations;
   d. 12 percent year-over-year improvement in postpartum care rates;
   e. 4.1 percent increase in well-child visits;
   f. 40 percent increase in member refill rates;
   g. 10-13 percent increase in antidepressant medication adherence.

Maintain Fiscal, Operational, Administrative and Compliance Healthcare Functions
Supporting providers in an emergency is critical to ensuring a strong healthcare infrastructure. Where possible, it is recommended that fiscal, operational, administrative and compliance functions are maintained, but adapted as necessary. Doing so ensures quality and safety of care and proper payment.

1. Increase communications with providers to identify critical needs.
2. Leverage audit activities that have low impact, such as automated edits, payment analytics and data mining.
3. Shift from onsite audits to desk audits, particularly among the most affected providers.

During an emergency, it’s imperative to stay connected with healthcare consumers, providing information relevant to the crisis at hand and their health and well-being.

1National Dialogue for Healthcare Innovation
4. Suspend clinical audits only in “hot spots” or among those providers affected by heavy patient loads.

5. Extend medical record and additional documentation deadlines as needed.

6. Provide additional days for providers to request audit appeals and to respond to technical denials.

7. Facilitate electronic transmission of medical records and documentation.

A robust post-emergency program integrity plan should also be implemented to fill program integrity gaps created by the emergency. An effective post-emergency plan:

1. Increases vigilance for fraudulent activities as schemes permeate healthcare during a crisis.

2. Revises audit mailing limits and extends look-back periods to capture any suspended audit activities during the emergency.

3. Develops new audits based on policy and programmatic changes made during the crisis that may be prone to fraud, waste or abuse.

Data and Evidence Generation

**HIPAA Changes Needed to Improve Public Health Access** to and sharing of select healthcare data can improve health surveillance before an emergency and inform response during a crisis.

Health Insurance Portability and Accountability Act (HIPAA) modernization is needed to achieve both.

1. Empower business associates to use protected health information (PHI) for public health purposes. Typically, business associates maintain data from multiple healthcare entities, but can only use and disclose PHI for certain services or functions on behalf of the covered entity and in accordance with the terms of the agreement between the two parties. Such agreements often do not permit business associates to disclose information or perform analytics on behalf of public health authorities, health oversight agencies, state and local health departments and state emergency operations centers. This authority was temporarily granted during COVID, but could help surveillance in advance of a crisis and better enable preventative measures if made permanent.

**Key Contacts**

- **Patient outreach & engagement:** Ellen Harrison, Sr. Vice President, Solutions & Data Ops; Jennifer Forester, Director, Medicaid Strategy, Solutions & Data Ops

- **Fiscal, operational, administrative compliance functions/telehealth oversight:** Dr. Gary Call, Sr. Vice President, Clinical Ideation; Dr. Timothy Garrett, Vice President, Clinical Ideation

- **HIPAA changes:** Omar Kilany, Vice President, Corporate Legal
COVID Active Research Experience (CARE)
IQVIA’s COVID-19 registry platform advances understanding, collaboration, and research

Response to a Global Pandemic
Since COVID-19 first emerged as a global pandemic, the pharmaceutical industry has risen to the challenge from a prevention as well as a treatment perspective. More than 160 vaccines went into development in 2020, and many existing therapies continue to be evaluated for their effectiveness in treating the virus. Much of what we know about the COVID-19 disease course comes from data collected from some of the most severe patients – those who require hospitalization. However, less is known about the virus’s symptoms, severity and duration experienced by non-hospitalized individuals or the treatments they are receiving outside the hospital setting. IQVIA launched the COVID Active Research Experience (CARE) Project in April 2020 to study the pandemic’s impact on people at the community level, and to provide insight into the natural history of the disease and risk factors that could define the reasons some patients suffer more severe effects than others.

Patient-Reported Insights on Covid-19
CARE follows the severity and duration of symptoms that participants are experiencing by relying on patient-reported insights. Responses to the longitudinal data collection may be used to provide insights on the length and severity of their illness, and the potential benefit or risks from specific medications or vitamin supplements on symptom severity, duration, or prevention of COVID-19-related illnesses. In a November article in Travel Medicine and Infectious Disease, IQVIA experts provide an exploratory analysis of how this data is used to characterize symptoms indicative of a positive COVID-19 viral test result outside the hospital setting.

The collection of CARE data cross-country enhances the generalizability of findings and adds strength to conclusions about benefits and risks.

This data will inform pharmaceutical organizations throughout the product development lifecycle by enabling pharma researchers to:
• Better understand symptom presentation, severity and the progression of COVID-19 in the general population, and provide reference or context for product safety;
• Understand what treatments patients are using for COVID-19 and other pre-existing comorbidities;

“By rapidly deploying this consumer registry, we can quickly aggregate the necessary data to enable invaluable insights that will ultimately inform better treatment measures.”
— Rob Kotchie, President, Real World Solutions, IQVIA

2020
CARE recruitment launched in U.S. (April)/ UK (July)

20K
Participants reported by smart phone, tablet, or PC in <6 months

550+
COVID-19 treatments in development

Source: Coronavirus Treatment Acceleration Program (CTAP)
• Evaluate and compare the effectiveness and safety of many treatments and vaccines;

• Study sub-populations of interest by using targeted recruitment strategies to expand the CARE population.

Analytic insights are available in near-real time based on the CARE registry. Person-generated health data from CARE can be enriched with secondary data sources, including medical and prescription claims, hospital-based data, electronic medical records and more, providing a solid body of data for understanding how COVID-19 impacts healthcare resource utilization, costs and clinically relevant outcomes.

**Patient Recruitment and Engagement**

Individuals are recruited via direct-to-patient approaches. Eligibility is based on potential exposure to COVID-19, not test results. Those who enroll in the study initially provide demographic and medical history information, and data on risk of COVID exposure, testing, symptoms and treatments, including non-prescription medications, vitamins and supplements. Afterward, registrants are periodically prompted to provide updated information about their symptoms and testing status, creating a picture of longitudinal symptom progression regarding the virus. Supplementary questions are later posed to identify recipients of COVID-19 vaccines.

Registry participants consent to be contacted for further follow-up and future real-world research opportunities. As a benefit of participation, the CARE Project provides access to participant dashboards that share results of the research, as well as links to safety and care guidelines.

In the U.S., a trusted process for tokenization is used to link the CARE Project data to real-world data on prescriptions, ambulatory care and hospitalizations. IQVIA applies its decades of experience handling sensitive health information for research purposes regarding this initiative, employing a wide range of methods to secure, handle and report information responsibly.

**FDA Scientific Partnership**

The FDA has contracted with IQVIA to provide agile analytics from the CARE registry to support better understanding of how people in the community are affected by exposure to the coronavirus and what treatments work best outside of hospital settings.

CARE data will be used by the FDA for early insights and deeper evaluation of research questions, as appropriate. These insights can, in turn, be used to guide evidence-based recommendations.

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**IQVIA**

Powered by the IQVIA CORE™, IQVIA leverages its healthcare expertise, data, analytics, and technology to help clients integrate human science expertise with advances in data science and technology to make better decisions that will advance human health.

**Contact Us**

CAREproject@iqvia.com
iqvia.com
Johnson & Johnson has been actively engaged in fighting pandemics and addressing times of crisis for over a century. We believe that with our global reach comes a responsibility and unique ability to leverage our deep scientific expertise and extensive partnerships to take this and other challenges on. Our more than 130,000 employees around the world have mobilized with urgency to address the critical needs of families, communities and healthcare providers working toward mitigating and ultimately ending the COVID-19 pandemic and responding to other natural disasters in 2020 and beyond.

**Preparedness**

Johnson & Johnson has been able to successfully support the needs of our customers, patients and communities despite the unprecedented challenges of COVID-19 and many other natural disasters this past year.

We attribute this track record of success to the incredibly robust Business Continuity Planning (BCP) we had in place prior to the pandemic. Our BCP includes maintaining critical inventory at distribution centers, working with external suppliers to support our preparedness plans and maintaining a geographically dispersed supply chain that has the ability to adapt as countries have implemented restrictions to contain the spread of the virus. We proactively monitor trends and develop actions to manage emerging or current risks including pandemics, natural disasters, cyber threats, terrorism, social unrest, geopolitical risks, import-export restrictions, regulations or disruption of sourcing.

Our processes also promote maintenance and testing of business continuity plans. Throughout the year, risk assessments, scans and surveys may be performed by the business and/or risk management functions to identify internal and external events that might affect achievement of Johnson & Johnson’s objectives. We are continuously strengthening our capabilities by providing BCP training for our employees, using unique scenarios and table-top exercises — ensuring our crisis management teams are ready to be activated across every region of the globe.

Several years ago, we created a structure of global, regional and local Crisis Management Teams (CMT). These teams guide and coordinate the process we follow to respond to disruptive events that may harm operations and the communities we serve.

The CMT structure enables us to gather and share information to safeguard our associates and support business continuity when man-made or natural disasters occur. The CMT teams are actively engaged to anticipate, plan for and resolve threats before, during and after they occur.

We also actively monitor our end-to-end supply chain during a major event like COVID-19 to ensure we are maximizing product availability, producing and delivering the right volumes of the medicines, devices, and consumer health products people need, in a safe, reliable and high-quality manner.

Examples include:

- Pre-positioning supplies;
- Pre-staging and pre-clearing alternate shipping methods and routes;
- Shifting orders to a different site or alternate manufacturer;
- Working cooperatively with our suppliers to expedite shipments;
- Negotiating to ensure free flow of goods and services across borders;
- Harnessing digital capabilities to monitor sales patterns and order flow to avoid unnecessary stockpiling that may lead to patient shortages;
- Ensuring coordination and intelligence gathering with appropriate Government partners.

In addition, we have made significant investments in digital and data science capabilities, which have enabled us to improve our end-to-end visibility throughout the value chain, allowing us to make better and faster trade-off decisions and ensuring we always put the needs of our patients and customers first.

In response to Hurricane Maria in late 2017, our Supply Chain team used digital tools to track the exact location of emergency supplies and products heading to or from the island of Puerto Rico to help automate business continuity efforts and ensure we continued to supply our products on time to our customers. We’ve applied this same approach in our response to the COVID pandemic and are working to enable end-to-end connected visibility for our entire portfolio.
Our teams are using highly automated scenario risk simulation technology to help minimize delivery disruptions. We are also using automated statistical scanning of sales order patterns to proactively handle abnormal demand patterns to help identify and subsequently prevent unnecessary stockpiling — ensuring we can continue to respond to and meet patient needs.

We also apply a variety of resiliency measures, ensuring:

- Continuity through dual sourcing for key manufacturing steps and dual source locations for key raw materials (or inventory);
- Maintain inventory levels by enabling alternate sites to cover demand, where available;
- Backup line(s) within existing sites (with available capacity) for key manufacturing steps;
- Sufficient inventory levels;
- Spare parts for critical equipment;
- BCP commitments for key primary and secondary suppliers.

Response
Since the early days of the outbreak, Johnson & Johnson has worked with industry partners, governments and health authorities to help end the fast-moving COVID-19 pandemic. Two of our most significant challenges in the last decade have been the current COVID-19 pandemic and the 2017 Atlantic hurricane season, which challenged us with multiple hurricanes in a row. How Johnson & Johnson responds depends on the identified needs and challenges of the crisis (examples below are not exhaustive).

COVID-19 Pandemic
Vaccine and Treatments: Building on the innovative science and scalable production platforms that were used to construct our approved Ebola vaccine and our investigational HIV and Zika vaccine candidates, we are working to evaluate the safety and effectiveness of our investigational COVID-19 vaccine with the ambition of delivering large volumes by early 2021.

- We are expanding our global capacity to support the goal of supplying more than one billion doses of the vaccine globally.
- Working with global partners we are screening a library of molecules, including antivirals, in order to identify potential treatments that could contribute to providing immediate relief to the current pandemic.
- Our infectious disease experts have provided guidance to entrepreneurs and the startup community embarking on COVID-19 related research and technologies. More than 60 resident companies in our global incubator network (Johnson & Johnson Innovation — JLABS) are currently exploring novel approaches to help address the COVID-19 pandemic.

Frontline Health Workers: In March 2020, the Johnson & Johnson Family of Companies and the Johnson & Johnson Foundation committed $50 million to support frontline health workers—from meals to protective equipment, extra training to mental health. This commitment expands upon a $250 million multi-year commitment we made earlier that year to support those at the frontlines.

Global Medical Personnel Leave Policy: Employees with needed medical skills may volunteer their time to serve their communities and our community health systems during the global pandemic.

Surge Capacity: As demand spiked the company ramped up production of critical medication and products by running manufacturing sites 24/7 and producing and shipping at all-time high rates, while maintaining high levels of safety, quality, and compliance. The company has taken all possible measures to maximize product availability and produce the highest volumes of the medicines people need right now, while prioritizing employee safety.

Product Donation: Millions of J&J products have been donated around the world across our Consumer Health, Medical Devices and Pharmaceuticals businesses. A few notable examples include the following:

- Ethicon, a Johnson & Johnson Medical Device Company, was able to leverage its manufacturing network, 3-D printing technology and a collaboration with Prisma Health to make and distribute a VESper™ Ventilator Expansion Splitter at no cost—going from concept and design to launch in just 10 days. The device, authorized by the U.S. Food and Drug Administration (FDA) for emergency use only, allows a single ventilator to be fitted with it and used for two resuscitable patients for ventilatory support during the COVID-19 pandemic until individual ventilators were available.
• In accordance with appropriate guidelines, including those from the Centers for Disease Control and Prevention and the FDA, Johnson & Johnson has converted some manufacturing lines at facilities around the world to produce hand sanitizer, which is helping to protect employees who work in research and development, manufacturing, and distribution. Hand sanitizer has also been donated to health and community service workers.

• With smokers at greater risk of contracting and suffering severe complications from COVID-19 due to their suppressed immune systems, Nicorette donated approximately $1 million in product via the World Health Organization.

Track and Tracing: Maximizing the ability of community health teams to conduct surveillance, contact tracing and rapid deployment of high-quality health information to communities and front-line health workers (FLHWs) through mobile tech, Johnson & Johnson Foundation has supported a range of mobile health partners: Dimagi, Praekelt.org, mHero, Mothers2Mothers and Reach52.

Health Disparities: We are working to advance racial and ethnic health equity through a series of targeted COVID-19 focused programs and partnerships which includes lending our voice expertise and perspective to improving health outcomes in Black communities.

2017 Atlantic Hurricane Season (Harvey, Irma, Maria and Nate)

Financial Support: In response to the multiple disasters affecting the U.S., the Caribbean, and Mexico, Johnson & Johnson donated $5.2 million and worked with more than two dozen external partners to support immediate, mid- and long-term response. In addition, over $6.6 million of Johnson & Johnson product was distributed within the regions impacted by these disasters.

Relief Supplies: Our pre-positioned general relief supplies (J&J relief kits, water, medicine) during Hurricane Maria, as well as household emergency items (generators, chain saws, food, water, batteries, camping stoves, etc.) enabled J&J to ship over 400 tons of relief and emergency supplies onto the island. In the early days of the storm, we were able to help our employees and their families get fuel and other vital supplies. J&J has also been able to install large water purification systems at our facilities across Puerto Rico, as well as ship ice machines we installed for food storage needs. Some of our garage parking was converted to house clothes washers and dryers.

Employee Giving: Johnson & Johnson enhanced charitable donation to relief organizations by matching employee and retiree giving 2-for-1 during the 2017 Atlantic season. J&J supported and also enabled employees to assist their own family and friends in Puerto Rico with direct shipment of emergency and personal supplies in the days after Maria. We expedited more than 300 individual air shipments and enabled 44 larger ocean shipments.

Supplier and Community Support: J&J assisted critical suppliers in need of generators, critical components and workers to help get their sites operational. In the early days of recovery when fuel was in short supply, we helped ensure police, first responders and local grocery stores had what they needed to stay operational. Our employees engaged across the island in the immediate aftermath repairing infrastructure, clearing roads, sharing contractors and equipment.

Frontline Healthcare Workers: J&J funded nursing programs to address resilience training and preparedness, as well as certain recovery needs.

J&J Home Share Program: Following Hurricane Irma, we launched a J&J Home Share Program a match-making service for employees to offer rooms in their homes to J&J colleagues displaced by the storm. More than 220 employees and retirees offered their homes and 450 beds were made available for J&J employees and retirees.

Conclusion
Over a century ago, Johnson & Johnson played a leading role in helping to limit the impact of the 1918 Flu, one of the deadliest pandemics in modern history. That commitment to patients, families, employees and communities during times of crisis continues today. As new challenges arise, we will continue to partner with governments and stakeholders across the globe to address immediate and long-term health care needs, supplying critical products for those who rely upon them. Our size, expertise, the investments we have made in our supply chain and the passion of our employees will, together, allow J&J to be there in times of need.
In keeping with its mission, Mayo Clinic is on the front line, leading the fight against COVID-19 and activating all its unique resources, research, diagnostics and therapeutics to help defeat the threat. In doing so, it is living its commitment to “finding solutions to the most difficult problems” to help bring the crisis to an end.

From the start of the pandemic, Mayo Clinic activated its Hospital Incident Command System (HICS) to centralize information flow and to direct resources. Through daily meetings of cross-functional staff, HICS has ensured the safety of patients and staff, monitored critical supply chains and deployed urgently-needed diagnostic tests.

Mayo also has partnered with experts, state and federal agencies, federal and state governments, and our communities to advise on the testing and treatment of patients, recommending how best to contain the spread of the virus and on how we can scale resources to meet the needs of our nation.

COVID Research Task Force

• Building on Mayo’s culture of team science collaboration and innovation, the SARS-CoV-2/COVID-19 research task force, led by Andrew Badley, M.D., coordinates all pandemic-related research activities and oversees independent, multidisciplinary teams headed by Mayo Clinic subject-matter experts.

The teams conduct research with live viruses, clinical trials, biological sample banking, develop molecular and antibody tests, investigate vaccine therapies, lead our nation’s experimental convalescent plasma program, perform sophisticated modeling predictions, and strive to reduce health disparities through community engagement. There are over 200 COVID research projects underway and over 300 COVID research publications expected by the beginning of this fall.

Partnerships

• In June, Mayo Clinic announced a partnership with Delta Airlines to increase safety for passengers and flight crew by reviewing, enhancing and continuously improving health and safety protocols as well as designing a workforce testing plan.

• Additionally, a team of preventative medicine specialists developed digital tools to improve contact tracing in order to prevent the spread of COVID within health care facilities. The team implemented a new approach to ensure the safety of the workforce and shared the uniform process as a framework for other health systems to replicate.

Virtual Health

• The ongoing COVID-19 pandemic has created an opportunity to radically transform the delivery of health care through telehealth so that patients can receive high-quality, more affordable and more accessible care at the right time and in the right location. In the first six months of the COVID-19 pandemic, Mayo Clinic conducted more telehealth visits per day than all telehealth visits combined in 2019. Access to this level of telehealth services was made possible by federal and state waivers creating flexibilities for originating site and geographic restrictions on telehealth services and permitting providers to practice across state lines.

• The Mayo Clinic Center for Connected Care positioned Mayo Clinic to adapt our workforce to meet the needs of patients and all for greater use of virtual health including two remote patient monitoring programs, for high-risk and low-risk COVID-19 patients.

From the start of the pandemic, Mayo Clinic activated its Hospital Incident Command System (HICS) to centralize information flow and direct resources. Through daily meetings of cross-functional staff, HICS has ensured the safety of patients and staff, monitored critical supply chains, and deployed urgently-needed diagnostic tests.
Patients at high risk for severe illness receive a cellular-enabled tablet to assess symptoms and devices such as a blood pressure cuff, thermometer, weight scale and pulse oximeter. Patients on the low-intensity monitoring program receive their care plan through the Mayo Clinic app, which sends notifications when it’s time to check in with their care team and assess symptoms related to COVID-19. Both programs ensure patients who are self-isolating still feel connected to their care teams at Mayo Clinic, who can monitor their data and provide additional virtual and in-person care as needed.

- In summer of 2020, Mayo Clinic launched an advanced care at home program, through which patients with conditions previously managed in a hospital will have the option to transition to a home setting and receive compassionate, high-quality virtual and in-person care and recovery services. The program has admitted patients with Covid-19, helping alleviate the pressure on hospitals during the surge of the pandemic.

Testing

- Since March 2020, Mayo Clinic Laboratories (MCL) has worked tirelessly to respond to COVID-19 with robust test development and processing. By redeploying laboratory staff to meet shifting demands and through diligent supply chain management, Mayo Clinic Laboratories performed 1.4 million polymerase chain reaction (PCR) tests, 221,000 serology, and 9,668 neutralizing antibody COVID-related tests between March and early September. They maintain the highest levels of test quality and validation and continue to serve as a partner in stopping the spread of COVID-19.

- In its home state of Minnesota, Mayo Clinic partnered with the University of Minnesota and the health department to co-lead a statewide testing partnership. This partnership executed a “moonshot” to provide robust testing throughout the state, largely supported by MCL’s capacity and resources. As of late September, MCL had performed over 723,000 molecular tests to support the Minnesota Partnership.

- Within that moonshot, MCL has leveraged its skills and expertise for key testing efforts, including testing partnerships with more than 440 long-term care facilities, 18 tribal nations in the state, 18 college and university health departments, and the Department of Corrections’ staff and inmates. MCL has also helped to host large community testing efforts at more than 60 locations and managed 15 testing locations in Minnesota in addition to previously established locations to increase access for under-served populations.

Tracking and Modeling

- Mayo Clinic introduced a tracking tool on MayoClinic.org featuring the latest COVID-19 data for every county in all 50 states and Washington, D.C., and Mayo Clinic insight on how to assess risk and plan accordingly. A team of Mayo Clinic data scientists worked to develop the content sources, validate information and correlate expertise in the tracker, all of which is enhanced with real-time data and predictive modeling so that communities can have access to reliable public health messaging rooted in science.

- Additionally, Mayo Clinic shares the data trends produced through predictive modeling with state and local governments to help inform their decisions about social distancing, masking and other measures to reduce viral spread and to know where more testing or medical resources are needed.
About McKesson
As a leader in U.S. pharmaceutical and medical supply distribution, McKesson stands at the forefront of healthcare supply chain innovation. Our vision is to improve care in every setting — one product, one partner, one patient at a time. The COVID-19 pandemic has reminded us all of the critical role medical distribution infrastructure plays during a health crisis. Our distribution network, with nearly 13 million square feet of space across approximately 70 distribution facilities, serves every U.S. state, Washington, D.C., and more than 250,000 points of care. We also pick, pack and ship more than 15 million packages directly to patients’ homes every year.

1. Material Preparedness — Ensuring the availability of supplies, pharmaceuticals and equipment in the case of a crisis, through expanded inventory, increased reserves and a comprehensive plan to maintain, track and retire products.

2. Supply Capacity Stewardship — Introducing nimble sourcing capabilities that identify manufacturing and raw material surge capacity and establish protocols to mobilize that supply through a scaled, agile network of diversified sourcing, vendor selection and qualifications.

3. Data, Communication and Coordination — Creating a centralized approach to view aggregated demand and supply data, giving visibility into what is being sourced, purchased and shipped at a moment’s glance. This approach will provide greater clarity on roles and allow for more coordinated contingency plans.

The COVID-19 pandemic has reminded us all of the critical role medical distribution infrastructure plays during a health crisis. Our distribution network, with nearly 13 million square feet of space across approximately 70 distribution facilities, serves every U.S. state, Washington, D.C. and more than 250,000 points of care.

Key Pillars of Disaster Preparedness for Supply Chain
The pandemic has also shown the world how public and private stakeholders can prepare for and react to future health crises. Having adequate funding in advance of a crisis is a key element of preparedness. Over the past several years, funding for bioterrorism and other emergency preparedness increased 250 percent. However, funding for pandemic influenza preparedness stayed relatively flat, below $500 million annually. McKesson believes an improved future state for disaster preparedness of the U.S. government should include three pillars:

1. Material Preparedness — Ensuring the availability of supplies, pharmaceuticals and equipment in the case of a crisis, through expanded inventory, increased reserves and a comprehensive plan to maintain, track and retire products.

2. Supply Capacity Stewardship — Introducing nimble sourcing capabilities that identify manufacturing and raw material surge capacity and establish protocols to mobilize that supply through a scaled, agile network of diversified sourcing, vendor selection and qualifications.

3. Data, Communication and Coordination — Creating a centralized approach to view aggregated demand and supply data, giving visibility into what is being sourced, purchased and shipped at a moment’s glance. This approach will provide greater clarity on roles and allow for more coordinated contingency plans.

McKesson’s Response
Helping Ensure Availability of Supply
From finding numerous new sources for personal protective equipment to manufacturing and sourcing protective gowns through a new partnership with Walmart, we are innovating and preparing our customers and the nation for future crises. In addition, we are enhancing the certainty of supply to provide distribution services, including stockpile solutions, to help make sure products are available when and where they are needed most. Lastly, our newly established “war room” is 100 percent dedicated to improving supply chain certainty — sourcing for national brands and private label, global sourcing and materials management.

Ramping Up to Distribute Critical Supplies Needed to Combat a Pandemic
As a global leader in healthcare distribution, McKesson has expanded its existing partnership with the Centers for Disease Control and Prevention (CDC) to support the U.S. government’s Operation Warp Speed (OWS) team as a centralized distributor of COVID-19 vaccines, and ancillary supplies needed to administer vaccinations. Vaccines and related supplies will be delivered to point-of-care sites across the country at the U.S. government’s direction.
Beyond distribution, manufacturers should develop plans for nimble, scalable production capacity; allowing them to ramp up production of critical medical supplies in a time of need. Providers should work in partnership with the government to define supply usage and conservation protocols that optimize for both safety and supply availability. The government would need to play a central role in aggregating and deploying a master view of inventory data. Further, the government should accelerate approval processes for product development and new manufacturer entries, as well as create incentives to increase the level of inventory throughout the supply chain.

Closing
McKesson stands ready to participate in the broad dialogue necessary to create a better approach to disaster preparedness. We are committed to partnering with the U.S. government, healthcare providers and other experts to innovate and improve our nation’s preparedness for, and response to, future health crises.

1 SOURCE: U.S. Department of Health and Human Services
2 SOURCE: Analysis of International Trade Center export data
A Mission as a Roadmap: Our Response to Covid-19

The COVID-19 pandemic has placed extraordinary pressure on healthcare systems, communities, economies and organizations of all sizes.

Using our Mission as a guide, we mobilized quickly to prioritize the well-being of our employees and their families. We partnered with others around the world to deliver essential products and support to the patients, healthcare professionals and communities that need them most.

Here we summarize some of our key responses to the pandemic that occurred during fiscal year 2020 (FY20). Our crisis response to COVID-19 will continue as long as needed, while we also work toward a sustainable recovery in the aftermath of this global emergency.

Safeguarding Our Employees
Our employees are the heart of our business. To address the unique needs of the 90,000+ people in our workforce during the pandemic, we have focused on targeted programs to ensure their safety and provided direct financial, health and well-being support.

Our cross-functional Crisis Response team has managed and coordinated our companywide response in line with our crisis management system.

Protecting Critical Employees
To help limit exposure to the virus, we acted to ensure employees in business-critical functions who cannot work from home were protected — including those in research and development, quality, manufacturing, distribution and the field. We implemented precautionary measures such as providing personal protective equipment (PPE), increased sanitation, social distancing guidance and facility updates such as one-way hallways, partitions at cafeteria tables and extra sinks.

Employee Programs and Benefits
To support our employees who were able to work from home, we have offered flexible working hours and provided a guide to thriving virtually.

Mental health support and new well-being tools — focused on food, finance, stress reduction, and fitness — were made available to all Medtronic employees. Companywide programs included:

- The Medtronic Emergency Leave Pay Policy, which allows employees to take up to 30 days of pay for certain scenarios related to COVID-19, unless local law or policy require otherwise;
- The Medtronic Employee Emergency Assistance Fund, which provides financial need-based grants to employees experiencing financial hardship, including childcare and any uncovered medical costs.

In addition to temperature checks and testing for employees working onsite, we have offered all employees in the United States and Puerto Rico a free Medtronic Care Management Services (MCMS) Virtual COVID-19 Care Evaluation and Monitoring Solution.

Supporting Patients and Healthcare Professionals
Our Mission to alleviate pain, restore health and extend life is more relevant than ever. We are helping to address the crisis by ensuring healthcare professionals have access to vital equipment to achieve better outcomes for COVID-19 patients.

Delivering Critical Products and Therapies
We accelerated production and distribution of essential products such as ventilators, pulse oximeters and extracorporeal membrane oxygenation machines. As of June 2020, we increased ventilator production fivefold from pre-pandemic production levels of less than 200 per week to 1,000 per week.

We put our Mission above competitive advantage and formed new collaborations to meet the critical global need for ventilators, resulting in partnerships with Foxconn, SpaceX and others. At the end of March, we published open-source design specifications for our portable, compact ventilator, the Puritan Bennett 560 (PB560). In the first few weeks, there were more than 200,000 downloads of the blueprint.
We also worked with the U.S. Food and Drug Administration to authorize emergency use of this ventilator in the United States.

**Partnering With Our Suppliers**
As countries began closing borders and restricting imports and exports to limit the spread of the virus, our global supply chain confronted extraordinary challenges.

We worked to help suppliers continue operating and ramp up production of critical components. Some invested millions in new equipment and infrastructure. Many hired more employees and shifted to 24/7 production to make parts.

Together, Medtronic and supplier teams worked quickly to:

- Secure government permission to operate as essential businesses;
- Obtain the paperwork needed to let employees travel to work;
- Increase production by acquiring additional raw materials and expanding workforces.

Carriers have prioritized medical product shipments, and some offer dedicated personnel to work exclusively with Medtronic freight.

**Providing Remote Tools, Essential Services and Capacity Building**
To help healthcare professionals reduce exposure and conserve limited resources such as PPE, we accelerated the development of a remote management capability of our Puritan Bennett™ 980 (PB980) ventilator. This software upgrade — developed within a matter of weeks — enables clinicians to adjust the ventilator settings away from the patient.¹ We have adapted several services and programs to support patients impacted by COVID-19 and those in high-risk groups, including:

- Expanding the Medtronic Assurance program to offer support to eligible diabetes customers who have lost health insurance due to COVID-19 related unemployment;
- Offering MCMS solutions to remotely assess potential COVID-19 symptoms, including for our employees, customers and U.S. health systems, health plans and employers;
- Extending the coverage and capability of our telehealth solutions, including remote monitoring of pulse oximeters, remote pacemaker programming and CareLink — our internet-based remote monitoring service for patients with implanted cardiac devices.

We have increased our focus on education for customers, patients and healthcare professionals. Since the start of the pandemic, we have delivered dozens of virtual physician forums and training programs, including remote ventilator training through the newly formed Ventilator Training Alliance.

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¹ This feature has not been cleared by the U.S. Food and Drug Administration (FDA). This feature was developed in accordance with the FDA Enforcement Policy for Ventilators and Accessories and other Respiratory Devices During the COVID-19 Public Health Emergency.
Investing in Health and Communities Around the World

As the coronavirus pandemic has unfolded, we have provided resources to help partners strengthen healthcare response and support underserved communities. In FY20, Medtronic and the Medtronic Foundation donated a combined $18.5 million to COVID-19 relief efforts, part of a larger pledge of more than $36 million that was announced in May 2020.

We recognize that minority communities are disproportionately affected by COVID-19. As a result, we have integrated our approach to inclusion, diversity and equity in our response to the pandemic.

Public-Private Partnerships

Many communities lack the resources and infrastructure to respond effectively to a health emergency such as COVID-19. Medtronic and the Medtronic Foundation have started working with key agencies and institutions, including the World Health Organization, FEMA, the G20 and the World Bank to:

• Assess and understand evolving needs;
• Prioritize access to Medtronic's and partners’ products;
• Provide additional assistance in the form of product donations or financial contributions.

Product Donation

We donated products to help a range of organizations and hospitals deliver lifesaving care to patients, including:

• Ventilators, respiratory filters and pulse oximeters to help patients recovering from COVID-19;
• PPE provided by our 3D Printing and Physiological Research Labs teams to protect healthcare workers.

Medtronic Foundation Giving

The Medtronic Foundation has made financial donations to:

• Dozens of global and local nonprofit organizations, equipping frontline health workers globally and investing in local response efforts to assist vulnerable populations
• Nearly 50 local community organizations and food banks providing critical resources and assistance to underserved populations worldwide
Introduction

MemorialCare is a nonprofit, fully-integrated health care delivery system located in Southern California that includes four hospitals and 200 ambulatory sites of care with 10,500 employees and 2,650 medical staff physicians. MemorialCare activated a systemwide multi-disciplinary team to lead its Command Center to plan and respond to COVID-19.

Story

“There is no ‘I’ in Team.”

In February 2020, with our infectious disease and quality experts warning of the SARS-CoV-2 virus’s characteristics and spread risk, MemorialCare assembled a multi-disciplinary group to serve on its systemwide Command Center. Like many across the U.S. and the globe, this team worked tirelessly and urgently to address the crisis and emergent needs of more than 1 million patients, 10,500 employees, 2,650 doctors, four hospitals and 200 ambulatory sites of care across Orange and southern Los Angeles Counties. The team’s first principle — “Keep our staff and physicians safe so that we can take safe care of our patients” — served as a guiding beacon for all decisions. We knew if our clinicians and staff were to fall ill, we would not be able to fulfill our Mission to improve the health and well-being of individuals, families and our communities.

Through October, this team has triaged and treated 55,360 symptomatic patients, performed 68,652 SARS-CoV-2 lab tests across 17 testing sites, sourced over 30 million PPE supplies, hosted 150 informational huddles and sent out more than 125 situation updates to our healthcare teams and Boards. Together, we’ve implemented over 40 Tip Sheets, set up a variety of Tender Loving Care systems for frontline care teams, adopted ethical crisis standards to handle “best use” of pharmaceuticals and treatments, reimplemented elective care safely once our Governor gave the go-ahead, and managed our financials and secured relief funding to stay afloat as a non-profit health system.

We believe what made this approach successful is the relative sense of calm and safety it created in “we’ve got this!”, the gratitude shared by all involved and outcomes achieved for MemorialCare’s communities, patients, staff and physicians. Leadership across the system stepped up, contributed to shared decisions, developed tools and processes and deployed them expeditiously to front-line teams.

The efforts of the Command Center — which is still going strong and ever-improving — has laid the foundation for success during this pandemic. By providing guidance, developing policies and overseeing operational needs, our community was kept safe, healthcare providers had the resources and support needed to administer care, quality data drove decisions and influenced innovation, and communication became the key to working across multiple entities.

Table: TEN principles to activate, maintain and continuously improve COVID-19 response.

Each principle was developed to ensure compassionate and safe care for our patients

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<tr>
<th>Principled leadership</th>
<th>How we activated</th>
<th>Keys to success</th>
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| 1. Keep staff and physicians safe so we can safely care for patients | Developed 10 Principles | • Evaluated principles in all decisions.  
• Created need for speed; brought in experts to gain consensus (e.g. infection prevention, lab, housekeeping, nursing, clinical care).  
• Collaborated with our Patient-Family Advisory Committees in all key decisions.  
• Sent staff home who could work remotely. |
| 2. Reducing spread is key | Implemented system-wide Tip Sheets for best practices in reducing spread | • Communicated rationale to connect hearts and minds “7 times, 7 ways”.  
• Met with physicians, leaders, staff from all specialties to understand and create plans to meet specific needs per patient care setting.  
• Shared “We’re Here, We’re Safe” messaging to our communities.  
• Partnered with other health systems on masking messaging to our communities.  
• Participated in research studies — Remdesivir (one of first five sites in US); Convalescent Plasma |
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| **3. Prevent unnecessary contact in all processes we design** | Factored into all decisions Lean design thinking | • Deployed Lean Fellows for system-wide redesign needs.  
• Transformed patient care, staff and visitor areas to ensure spacing, proper flow and safety.  
• Created triaging system — “Purple — Orange — Green zones” — enabling separation of patients between those with virus, those suspected, and those virus-free.  
• Leveraged telehealth — ambulatory and in-hospital (e.g., 161,500+ virtual visits; iPads connecting patients with family). |
| **4. Follow Hospital Incident Command System (HICS) structure** | Created centralized HICS Command Center, with Incident Commander (IC) role plus back-ups for the IC and key workstream leads | • Established 15 Workstreams: Communications, Supplies, Infection Prevention, Workforce, Laboratory, Ambulatory, Treatment, Procedures, Education, Clinical Practice, Facilities, Advocacy, Finance, Surge, Tender Loving Care  
• Met three times daily: “the 0700” review with 150+ enterprise-wide leaders; “the 0930” focused Command Center to triage issues, “the 1700” to report back out on daily decisions and communication plan.  
• Evolved frequency to meet needs. |
| **5. Clear delineation of what is systemwide decision versus local** | Established rationale for what is system-wide versus local decision-making | • Gained agreement: priority to learn and develop system-wide, with implementation influenced by local needs and supervised by cascading Command Centers’ COO, CMO and CNO leadership (e.g. physical layout, patient types). |
| **6. Share creative ideas** | Created daily management system for site report in: key learnings, tests of change, needs | • Built in agenda at all systemwide meetings to hear all parties’ needs and ideas. |
| **7. Leverage LEAN e-mail, texting** | Established “rules of the road”: triaging ideas, needs, concerns | • Created triaging system into local Command Centers and up to system Command IC; reviewed and coordinated incoming needs. |
| **8. If off-line, let team know** | Created “compact” to know who to contact; hard-wiring in days off | • Set up system to inform when leaders off-line.  
• Required leaders take day off every one-to-two weeks to recharge; designated back-up. |
| **9. Realize 24/7 need between now and when ends** | Pledged to teams, physicians, Boards to address needs 24/7 | • Leveraged “0700, 0930, 1700” to assure tracking all issues.  
• Each site communicated in shift huddles on issues and opportunities for improvement. |
| **10. Assume good intent; take care of each other** | Utilized to address “conflicting opinions” | • Most valuable principle besides #1; used routinely to combat stress, assure best decisions. |
Overview of Current Merck Practices

- Merck's essential mission is to invent and manufacture medicines that save and improve lives. Given this commitment, Merck takes a rigorous and comprehensive approach to crisis and disaster response and business continuity planning, ensuring the company’s ability to respond effectively to disruption and restore essential services during or after a man-made or natural disaster, such as an epidemic or pandemic, hurricane or wildfire, or civil unrest.

- Merck employs a robust enterprise risk management program, which includes crisis and disaster response strategies. This program emphasizes identification of potential risks, mitigation of known risks, and ensuring recovery preparedness. A cross-functional team of senior executives is responsible for crisis response leadership.

- In addition to its overall strategic oversight as part of Merck’s enterprise risk management program, our approach to business continuity planning includes a centralized framework focused on critical business processes ensuring our ability to recover from any type of business disruption to facilities, technology, people or third-party suppliers. The approach harmonizes business continuity, IT disaster recovery and emergency response protocols ensuring linkage across the enterprise. Development of each site-specific business continuity plan includes an assessment of facility-specific risks and potential business impact, recovery strategy analysis and continuity planning, and continuous review and improvement.

Merck takes a rigorous and comprehensive approach to crisis and disaster response and business continuity planning.

Hurricane Maria

- In September 2017, Hurricane Maria devastated Dominica, St. Croix, and Puerto Rico. A category 5 hurricane, Maria claimed more than 3,000 lives, including 2,975 in Puerto Rico. Merck’s presence in Puerto Rico is significant and includes a major manufacturing facility in Las Piedras. The Las Piedras facility manufactures multiple medicines for dozens of markets around the world.

- Prior to Hurricane Maria’s landfall, the Las Piedras facility was secured per successful execution of its site-specific business continuity plan, including accomplishment of key tasks such as data backup, securing of raw materials and shipment of finished product.

- The scale of on-site recovery efforts after the storm was unprecedented and included tasks ranging from the shipment of large generators from other Merck sites to the distribution of satellite phones to employees who were without normal means of communication.

- Despite these significant headwinds, the Las Piedras facility resumed operations only 14 days after Maria’s landfall.

Drone Delivery

- In Maria’s aftermath, many Puerto Ricans were completely cut off from essential services, including access to medicines. Researchers estimate that most deaths from Maria were caused by loss of access to medicines and health care, not by wind or water.

- With the goal of helping to mitigate this problem in future disasters of similar scale, and as part of our commitment to continually improving our disaster preparedness and business continuity protocols, Merck conceived of and began work on an initiative to develop drug and vaccine delivery capabilities via drone in late 2017.

- Drone delivery of drugs and vaccines is not without significant challenges; most crucially, many medicines have strict refrigeration requirements that must be maintained at all points in the supply chain. These hurdles notwithstanding, together with its drone partner, Volansi, Merck conducted its first island-to-island drone test flights in August 2018.

- Merck continues to develop its drone delivery concept and capabilities, with the objective of offering drug and vaccine delivery by drones in rural areas, increasing access to Merck lifesaving medicines across the globe, serving underdeveloped areas with poor logistical capabilities and helping to respond to geographies impacted by disasters.
Mount Sinai Develops Machine Learning Models to Predict Critical Illness and Mortality in COVID-19 Patients

Mount Sinai researchers have developed machine learning models that predict the likelihood of critical events and mortality in COVID-19 patients within clinically relevant time windows. The new models outlined in the study — one of the first to use machine learning for risk prediction in COVID-19 patients among a large and diverse population, and published November 6, 2020 in the *Journal of Medical Internet Research* — could aid clinical practitioners at Mount Sinai and across the world in the care and management of COVID-19 patients.

“From the initial outburst of COVID-19 in New York City, we saw that COVID-19 presentation and disease course are heterogeneous, and we have built machine learning models using patient data to predict outcomes,” said Benjamin Glicksberg, Ph.D., Assistant Professor of Genetics and Genomic Sciences at the Icahn School of Medicine at Mount Sinai, member of the Hasso Plattner Institute for Digital Health at Mount Sinai and Mount Sinai Clinical Intelligence Center (MSCIC), and one of the study’s principal investigators. “Now in the early stages of a second wave, we are much better prepared than before. We are currently assessing how these models can aid clinical practitioners in managing care of their patients in practice.”

In the retrospective study using electronic health records from more than 4,000 adult patients admitted to five Mount Sinai Health System hospitals from March to May 2020, researchers and clinicians from the MSCIC analyzed characteristics of COVID-19 patients, including past medical history, comorbidities, vital signs and laboratory test results at admission, to predict critical events such as intubation and mortality within various clinically relevant time windows that can forecast short- and medium-term risks of patients over the hospitalization.

The researchers used the models to predict a critical event or mortality at time windows of 3, 5, 7 and 10 days from admission. At the one-week mark — which performed best overall, correctly flagging the most critical events while returning the fewest false positives — acute kidney injury, fast breathing, high blood sugar and elevated lactate dehydrogenase (LDH) indicating tissue damage or disease were the strongest drivers in predicting critical illness.

Older age, blood level imbalance and C-reactive protein levels indicating inflammation were the strongest drivers in predicting mortality.

“We have created high-performing predictive models using machine learning to improve the care of our patients at Mount Sinai,” said Girish Nadkarni, M.D., Assistant Professor of Medicine (Nephrology) at the Icahn School of Medicine, Clinical Director of the Hasso Plattner Institute for Digital Health at Mount Sinai, and Co-Chair of MSCIC. “More importantly, we have created a method that identifies important health markers that drive likelihood estimates for acute care prognosis and can be used by health institutions across the world to improve care decisions, at both the physician and hospital level, and more effectively manage patients with COVID-19.”

About the Mount Sinai Health System

The Mount Sinai Health System is New York City’s largest academic medical system, encompassing eight hospitals, a leading medical school and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care — from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report’s* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in the country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians in the top 1 percent of all physicians nationally by *U.S. News & World Report*. 
ICAP at Columbia University and the Dalio Center for Health Justice at NewYork-Presbyterian have announced the launch of the REACH (Responding to Epidemics and Crises in Health) Fellowship.

This innovative, one-year program will provide a select group of NewYork-Presbyterian staff across a variety of health disciplines an opportunity to learn how to predict, manage and lead robust responses to complex health emergencies, including emerging infectious diseases and other health crises.

“The COVID-19 pandemic has brought into a sharp focus the need to train a new generation of health professionals fully equipped to manage the complexities of sudden health crises, especially those involving emerging new infectious diseases,” said Wafaa El-Sadr, M.D., MPH, MPA, founder and global director of ICAP, the global health center at Mailman School of Public Health. “The REACH fellowship will leverage the expertise of NewYork-Presbyterian and ICAP to provide comprehensive training to enable health workers to react and respond quickly and confidently to a wide range of health emergencies.”

“I am keenly aware of the commitment, hard work and sacrifice our staff has made and continues to make to address COVID-19,” said Steven J. Corwin, M.D., President and Chief Executive Officer of NewYork-Presbyterian. “The REACH Fellowship will allow us to distill the lessons learned during this pandemic and to work towards creating institutions and a workforce that is ready and prepared to address the challenges of tomorrow.”

The REACH Fellowship will offer a range of approaches to bring the fullest level of education and training to the fellows. This includes tailored coursework, lectures and case studies around topics such as global health, epidemiology, social determinants of health, epidemic preparedness and response, and health communication, as well as skill-building seminars. Fellows are paired with expert mentors and peers as they work on capstone projects relevant to their specific discipline and interest.

Candidates are nominated by their senior vice presidents at NewYork-Presbyterian and are drawn from a highly competitive pool of early and mid-career professionals from across the NewYork-Presbyterian enterprise.
Nominees are welcomed from a wide array of disciplines including, but not limited to, nursing, medicine, social work, laboratory services, infection prevention and control, facilities, logistics and supply chain, surveillance, workforce health and safety, and public relations/communications.

Nominations will be accepted in November 2020, for a start date in late January 2021.

About ICAP
A global health leader since 2003, ICAP was founded at Columbia University with one overarching goal: to improve the health of families and communities. Together with its partners—ministries of health, large multilaterals, health care providers and patients—ICAP strives for a world where health is available to all. To date, ICAP has addressed major public health challenges and the needs of local health systems across more than 30 countries.

About the Dalio Center for Health Justice
The Dalio Center for Health Justice at NewYork-Presbyterian is dedicated to understanding and improving health equity, addressing health justice and driving action that results in measurable improvements in health outcomes for all. The center aims to reduce health disparities that disproportionately affect communities of color. A convener, collaborator and grantor, the Dalio Center for Health Justice brings together renowned experts in diverse fields to fuel change and support health justice among NewYork-Presbyterian team members, our patients and communities, and ultimately local and national policy.

The Dalio Center for Health Justice was established with support from Dalio Philanthropies, whose founder, Ray Dalio, is a NewYork-Presbyterian Trustee and an important thought partner behind the Center.

NewYork-Presbyterian
NewYork-Presbyterian is one of the nation’s most comprehensive, integrated academic healthcare systems, encompassing 10 hospital campuses across the Greater New York area, more than 200 primary and specialty care clinics and medical groups, and an array of telemedicine services.

A leader in medical education, NewYork-Presbyterian Hospital is the only academic medical center in the nation affiliated with two world-class medical schools, Weill Cornell Medicine and Columbia University Vagelos College of Physicians and Surgeons. This collaboration means patients have access to the country’s leading physicians, the full range of medical specialties, latest innovations in care, and research that is developing cures and saving lives.

Ranked the #4 hospital in the nation and #1 in New York in U.S. News & World Report’s Best Hospitals rankings, NewYork-Presbyterian Hospital is also recognized as among the best in the nation in the U.S. News Best Children’s Hospitals rankings. Founded nearly 250 years ago, NewYork-Presbyterian Hospital has a long legacy of medical breakthroughs and innovation, from the invention of the Pap test to pioneering the groundbreaking heart valve replacement procedure called TAVR.

NewYork-Presbyterian's 47,000 employees and affiliated physicians are dedicated to providing the highest quality, most compassionate care to New Yorkers and patients from across the country and around the world.
Pfizer Outlines Five-Point Plan to Battle COVID-19

On March 13, 2020 Pfizer issued a five-point plan calling on the biopharmaceutical industry to join the company in committing to unprecedented collaboration to combat COVID-19.

Albert Bourla DVM, Ph.D., Pfizer Chairman and CEO, made the following statement: “In this troubling time, Pfizer is committed to doing all we can to respond to the COVID-19 pandemic. Many companies, including Pfizer, are working to develop antiviral therapies to help infected patients fight this emerging virus as well as new vaccines to prevent infection and halt the further spread of this disease. Pfizer is working to advance our own potential antiviral therapies and is engaged with BioNTech on a potential mRNA coronavirus vaccine. We are committed to work as one team across the industry to harness our scientific expertise, technical skills and manufacturing capabilities to combat this evolving crisis.”

Pfizer has made five promises that will help scientists more rapidly bring forward therapies and vaccines to protect humankind from this escalating pandemic and prepare the industry to better respond to future global health crises.

1. **Sharing Tools and Insights:** With very little known about this virus, many have worked to develop cell-based assays, viral screening, serological assays and translational models to test potential therapies and vaccines. Pfizer is committed to making the vital tools we develop available on an open source platform to the broader scientific community and to sharing the data and learnings gained with other companies in real time to rapidly advance therapies and vaccines to patients.

2. **Marshalling Our People:** Human capital is our most valuable resource. Pfizer has created a SWAT team of our leading virologists, biologists, chemists, clinicians, epidemiologists, vaccine experts, pharmaceutical scientists and other key experts to focus solely on addressing this pandemic. This team applies their passion, commitment and expertise to a single focus of accelerating the discovery and development process that will deliver therapies and vaccines to patients as soon as possible.

3. **Applying Our Drug Development Expertise:** Many smaller biotech companies are screening compounds or existing therapies for activity against the virus causing COVID-19, but some lack the experience in late stage development and navigating the complex regulatory systems. Pfizer is committed to sharing our clinical development and regulatory expertise to support the most promising candidates these companies bring forward.

4. **Offering Our Manufacturing Capabilities:** Once a therapy or vaccine is approved, it will need to be rapidly scaled and deployed around the world to put an end to this pandemic. As one of the largest manufacturers of vaccines and therapeutics, Pfizer has committed to using any excess manufacturing capacity and to potentially shifting production to support others in rapidly getting these life-saving breakthroughs into the hands of patients as quickly as possible.

5. **Improving Future Rapid Response:** Finally, to address future global health threats, Pfizer has reached out to federal agencies including NIH, NIAID and CDC to build a cross-industry rapid response team of scientists, clinicians and technicians able to move into action immediately when future epidemics surface.”In recent years, the biopharmaceutical industry has brought forward some of the most impactful medical breakthroughs known to society, from therapies for HIV and cancer that have extended millions of lives to novel gene therapies that are seeing cure-like outcomes for some of the most devastating rare diseases,” said Dr. Bourla.

“Pfizer is working to advance our own potential antiviral therapies and is engaged with BioNTech on a potential mRNA coronavirus vaccine. We are committed to work as one team across the industry to harness our scientific expertise, technical skills and manufacturing capabilities to combat this evolving crisis.”
“Pfizer calls on all members of the innovation ecosystem — from large pharmaceutical companies to the smallest of biotech companies, from government agencies to academic institutions — to commit to work together in addressing this dire crisis. With our combined efforts we know that there is no health challenge that we cannot overcome.”

Disclosure Notice: The information contained in this release is as of March 13, 2020. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer’s efforts to battle COVID-19 that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including uncertainties regarding the results of screening and the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable pre-clinical or clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications for any potential antiviral compounds may be filed or approved in any jurisdictions, which will depend on myriad factors, including making a determination as to whether the product’s benefits outweigh its known risks and determination of the product’s efficacy; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of any such products; our manufacturing capabilities; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.
Premier’s Response to COVID-19

For more than two decades, Premier has been a trusted connection point for healthcare providers, suppliers, manufacturers, distributors and the government.

Throughout the COVID-19 pandemic, we’ve set aside competitive boundaries and leveraged our relationships at every level of the supply chain to address challenges and enable access to lifesaving healthcare supplies, intelligence and technology.

_**Early Activation:**_ Beginning on January 23, 2020, three weeks before the first U.S. COVID-19 patient was identified, Premier’s Disaster Response Team mobilized. This early activation provided Premier and our member hospitals and health systems an edge in anticipating the explosion of global demand for critical personal protective equipment (PPE).

_**Health System and Provider Communication:**_ By March, with U.S. COVID-19 cases on the rise and supplies dwindling, Premier began hosting weekly member calls to share the latest updates, best practices and guidance — and conducted nearly a dozen surveys with our members to assess their PPE, lab testing, advocacy and pharmacy needs. With a footprint of more than 4,100 hospitals and 200,000 non-acute sites of care, this primary research and continuous member dialogue helped us understand early gaps, advocate for favorable policy and innovate solutions. Our data kept government leaders informed in real-time of the on-the-ground situation, and ultimately led to the creation of private-sector initiatives that accelerated product delivery to hospitals and health systems with the greatest need.

_**Private Sector Supply Chain Coalition:**_ One such initiative — launched and led by Premier — is the Private Sector Supply Chain Coalition, which unites more than 20 organizations across the healthcare supply chain (distributors, GPOs, manufacturers) to facilitate rapid coordination with the federal government, increasing the distribution of critical medical supplies, equipment and life-saving drugs to healthcare providers and frontline workers. Since early March 2020, the coalition has been working with dozens of agencies across the federal government on strategies to gather data, forecast demand, identify needed regulatory changes, preserve inventory, increase available supplies, allocate based on need and play a critical hand in programs such as the ventilator exchange.

**Sourcing High-Quality Products:** Beyond coalition leadership, Premier has been working with suppliers worldwide to ramp up production — some more than double or triple historic demand levels — and implemented a range of strategies to obtain vital products.

A component central to this response effort was the solid groundwork Premier began laying over a decade ago to diversify sourcing. Through S2S Global, our factory-direct sourcing company, we work with manufacturers in their country of origin to produce high-quality products to our members’ specifications. When PPE demand surged from March to May, S2S identified seven different PPE factories around the globe to secure 36 million masks and respirators and 16 million gowns. Our forward buys have gone on to secure sourcing for 130 million masks and 50 million gowns in 2020. Via our generic drug sourcing program ProvideGx, Premier took action to ensure members had access to the pharmaceuticals they needed, as well — maintaining our historic 100 percent fill rates for 10 critical pandemic drugs, despite more than 150 percent surge demand in some cases.

**Expedited Supplier Contracting:** To safely accelerate new entrants and products to the market, Premier reduced the days to bring new suppliers onto contract to 14 days or fewer for categories experiencing product allocation or shortage, and we have brought on 100 new suppliers since the pandemic hit. And when nearly three out of five hospitals told Premier they had received a gray market PPE solicitation, we used our expedited sourcing process to safely vet gray market solicitations on behalf of our members, determining less than 10 percent were legitimate.

Throughout the COVID-19 pandemic, we’ve set aside competitive boundaries and leveraged our relationships at every level of the supply chain to address challenges and enable access to lifesaving healthcare supplies, intelligence and technology.
**Domestic Manufacturing and Product Exchange:** In addition to an effective, diverse sourcing approach, another essential element to the COVID-19 response includes ramping up U.S. manufacturing capacity. For instance, after learning that 90 percent of all face masks were produced in China and susceptible to shortage, Premier and 15 leading health systems took a minority stake in Prestige Ameritech, the nation’s largest domestic producers of face masks as well as other PPE. In exchange for the investment and long-term commitment to purchase, the company is now making 3.5 million masks per month for our members. Premier, in partnership with Resilinc and Stanford University, also created an online exchange for U.S. health systems to dynamically trade PPE supplies within the United States — with more than 1,000 provider participants and more than 5 million products available.

**COVID Predictive Surveillance Tool:** By late April, as hospitals began preparing for the resumption of elective procedures, Premier rolled out predictive technology solutions that anticipate COVID-19 case surges along with specific supply implications. Our automated, real-time surveillance app integrates with existing electronic health records (EHRs) from different companies, thereby providing early warning capability, forecasting surges and helping providers plan coordinated responses. Our supply chain forecasting and planning tool also aggregates both clinical and supply chain data and applies insights to individual hospitals, offering near real-time information to guide decision-makers’ preparations in predicting surge, prioritizing supply and adjusting therapies for COVID-19 patients.

**Speeding Testing Resources:** Alongside the resumption of elective surgeries in spring 2020 also came the need to increase COVID-19 testing capacity. To that end, an April survey found that hospitals’ testing capacity would need to at least triple before resuming full services, and nearly 60 percent of respondents sought more fact-based guidance on COVID-19 testing. With the need for rapid leadership in the space, Premier stood up the COVID-19 Testing Advisory Panel to create testing plan best practices, rapid response strategies and recommended use cases for testing technologies.

As of November 2020, we’ve vetted 140 tests and brought on nearly 20 new diagnostic contracts to broaden availability for our members.

The COVID-19 pandemic rapidly shifted the way providers had to obtain supplies and deliver care. The National Institutes of Health has also leveraged Premier’s technology and robust data to better understand the pandemic’s impact on therapeutic areas, and to evaluate the effectiveness of treatment options.

**Successful Advocacy for Regulatory Reforms:** With its early insights on the market and boots-on-the-ground work in garnering vital products and supplies, Premier provided guidance on new trends and consistently advocated for providers’ needs. In all, we achieved more than 45 regulatory reforms and reimbursement changes related not just to telehealth, but also drug compounding, access to private label drugs in 340B, flexibilities for value-based purchasing programs and alternative payment models, PPE conservation protocols and many more. We’ve launched new services to help our members moderate the financial impact of COVID-19, and continue to advocate for more rapid adoption of alternative payment models that better insulate providers’ finances and demonstrate better-quality outcomes.

As part of our collective past efforts, and in looking ahead, Premier remains focused on serving our members and the healthcare industry at-large — stabilizing the supply chain, providing an early warning of COVID-19 hotspots, bridging the public and private sectors and promoting industrywide problem-solving and advancements. Premier has an unwavering commitment to innovating solutions, enhancing technology and creating partnerships that aid providers and healthcare workers when they need it most.
Taking a Collaborative Approach to COVID-19 — Metropolitan Pandemic Task Force

Overview

• When COVID-19 became prevalent in the United States, it changed all aspects of our lives, including how we care for our patients. In April 2020, the St. Louis region’s largest health care systems began working to better serve the community as the St. Louis Metropolitan Pandemic Task Force.

• The task force includes members of BJC HealthCare, Mercy, SSM Health and St. Luke’s Hospitals, public health departments, elected leaders and state and federal agencies.

• The regional team collaborates to create and implement robust plans to address regional policies, assisting business and schools with mitigation strategies, planning for a surge in COVID-19 cases, staffing resources, capacity concerns, ventilator shortages, testing and other critical supplies.

In April 2020, the St. Louis region’s four largest health care systems came together with elected leaders, civic and business leaders and public health agencies to address the COVID-19 pandemic.

Background

• In April 2020, the St. Louis region’s four largest health care systems came together with elected leaders, civic and business leaders and public health agencies to address the COVID-19 pandemic. This collaboration ensured the best possible patient care, staffing resources, allocation of supplies and that hospital beds and other critical assets were coordinated during the pandemic.

• Goals:
  • To protect the overall health and well-being of the community and interrupt the transmission of COVID-19 to save lives.
  • Address the COVID-19 threat in a way that allows government and health officials to make the best possible decisions regarding shelter-in-place orders and other social and economic mitigation factors.
  • To provide accurate and current data from the St. Louis region’s health care systems to help educate the community about the pandemic in real time.
  • To work together as a region to help avoid situations that could overwhelm our health care system and hospitals, that could lead to a deficit in staffing, supplies and capacity or bed space.

Description

• The task force is led by Alex Garza, M.D., Chief Community Health Officer at SSM Health. Dr. Garza, whose background includes serving as a colonel in the Army Reserve, is a board-certified emergency physician and worked under President Obama in the Department of Homeland Security, leading the country’s H1N1 efforts.

• In April 2020, the task force began holding daily media briefings to inform the community about the virus and ways to help stop the spread by using mitigation factors and CDC guidelines, such as social distancing, wearing a mask and practicing good hand hygiene. The briefings also addressed real-time data — for daily hospital admissions and discharges, hospitalizations, and ventilators and ICU beds in use by patients with COVID-19.

• A few of the biggest challenges facing the task force have included the increase of COVID-19 cases and the differing executive orders in surrounding communities and neighboring states.

• Task force hospitals have neared capacity as flu season approached. The task force has sought further adoption of mitigation measures for such circumstances.
Value and Metrics

- The St. Louis Metropolitan Pandemic Task Force has strengthened the relationship between our region’s leading health care systems and provided support during times of uncertainty. Barriers were removed, and collaboration and sharing of resources created a community approach, instead of silos. This may lead to more post-pandemic collaboration related to social determinants of health in our communities.

- In addition, government leaders have leaned on the task force for mitigation strategies, guidelines and best practices.

- A bond of trust has formed with the community as people look to the task force to provide guidelines on how to keep themselves and their families safe.

- The following graphs represent the COVID-19 cases in the Metropolitan Statistical Area of the St. Louis region — including St. Louis City and the counties of St. Louis, St. Charles, Jefferson, Franklin, Lincoln and Warren in Missouri, and the Illinois counties of St. Clair, Madison, Bond, Calhoun, Clinton, Jersey, Macoupin and Monroe.

As of November 4, 2020
KatrinaHealth
When Hurricane Katrina devastated the Gulf Coast in 2005, Surescripts joined an industry-wide effort to coordinate care for impacted patients. Through a single portal, KatrinaHealth.org, pharmacists and prescribers could gain access to medication history for patients who were forced to evacuate. Having this information helped patients renew medications and avoid potential prescription errors, as an estimated 40 percent of evacuees used one or more prescription medications before the storm hit. At the time, Surescripts delivered patient medication history information based on pharmacy-fill data from 90 percent of pharmacies nationwide. The data provided by Surescripts often contained additional information about the prescriptions, such as dose and quantity, administration, interactions, allergies, prescriber name, the pharmacy where it was filled and whether refills were available. KatrinaHealth was supported by federal, state and local governments, a national foundation, private businesses, and national trade associations. Within the first 60 days, KatrinaHealth fielded nearly 5,000 queries from doctors and pharmacists.

Hurricanes Harvey and Irma
In 2017, thousands of residents throughout the Gulf Coast were displaced from their homes due to the massive flooding that resulted from Hurricanes Harvey and Irma. Many pharmacies, hospitals, clinics and doctor’s offices were closed, and patients needed to reconnect with their care regimens in new settings. In fact, Surescripts data showed a 93 percent decrease in the volume of prescriptions delivered in the days immediately following Hurricane Harvey.

In response, Surescripts assembled a team to focus on efforts to aid recovery wherever possible. Surescripts activated its disaster plan to ensure that its nationwide pharmacy directory was up to date and reminded prescribers that they could access medication history through their EHR to help recover prescription information.

Surescripts also provided data and insights on prescribing activity in the area to the federal government to help inform its response plans. When a number of states declared a state of emergency temporarily allowing pharmacists to dispense critical medications without a prescription, Surescripts quickly mobilized its network to help. Together with Allscripts, Surescripts enabled any pharmacist in affected regions — regardless of what technology platform they used — to access patient medication history data through a free, cloud-based application. Access to this medication history allowed pharmacists to quickly and accurately process refills for patients impacted by the hurricane. The service was also made available to prescribers who didn’t already utilize medication history data through their EHR software.

Surescripts partnered with major pharmacy benefit managers and retail pharmacy chains, the National Community Pharmacists Association (NCPA) and National Association of Chain Drug Stores (NACDS) to raise awareness of the availability of the service among large and small pharmacy chains. Surescripts also worked with Healthcare Ready to share information with its network of public partners, including Disaster Medical Assistance Team pharmacists.

Together with Allscripts, Surescripts enabled any pharmacist in affected regions — regardless of what technology platform they used — to access patient medication history data through a free cloud-based application. Access to this medication history allowed pharmacists to quickly and accurately process refills for patients impacted by the hurricane.
Impact of Hurricanes on E-Prescribing Access
Following Hurricanes Harvey, Irma and Maria, Surescripts conducted a study of e-prescription and medication history transaction data to better understand providers’ access to these technologies across affected regions. At the time, accessing healthcare was nearly impossible in some areas, and widespread power outages made access to the technology that enables it extremely difficult.

Surescripts network data provided an in-depth look inside healthcare during a natural disaster—when healthcare providers still need access to patient information in order to care for patients safely and efficiently. The study shed light on opportunities to strengthen the healthcare ecosystem and the infrastructure that supports it. These insights can help inform the federal government’s response and recovery efforts and point to improvements that may be needed to restore more quickly essential medical services.

COVID-19 Response
In early 2020, Surescripts worked with the U.S. Food and Drug Administration (FDA) to provide de-identified, aggregated reports on prescription trends in response to questions from the agency related to COVID-19 while complying with all applicable privacy laws and regulations. While the reports Surescripts shared do not include protected health information (PHI), the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) had taken action to permit good faith uses and disclosures of PHI by business associates for public health and health oversight activities during the COVID-19 national emergency.
The Value of Relationships

Background
The COVID-19 pandemic exposed significant gaps in social and community-based services that the United States has traditionally relied on for disaster assistance. Breakdowns in fundamental infrastructures, such as supply chains, technology, and healthcare services were not only exposed but televised, with citizens in lockdown seeing images of empty grocery store shelves, overwhelmed hospitals, and long-lines for COVID-19 testing. The results have been an increased level of fear and distrust, especially within some of our most vulnerable populations, notably senior citizens. Given the sudden onset and complex impacts of the pandemic, disaster planning and response must include comprehensive communications and nimble methods to identify, prioritize, and respond to special population needs and groups that are more at risk. Building trust and credibility with constituents and having strong public-private partnerships before and after a disaster is a critical component shown to optimize a crisis response and to accelerate business reopening.

Given the sudden onset and complex impacts of the pandemic, disaster planning and response must include comprehensive communications and nimble methods to identify, prioritize, and respond to special population needs and groups that are more at risk.

Description of Program
SilverSneakers®, by Tivity Health, is the nation’s leading community fitness and healthy aging program for older Americans. For nearly three decades, SilverSneakers has provided fitness programs delivered by caring, trained instructors to millions of older adults.

Funded by Medicare Advantage and in collaboration with health plans, our commitment to and focus on the unique needs of older adults has established SilverSneakers as a trusted brand among 16 million eligible members. SilverSneakers also plays a significant role in addressing social connectivity and reducing social isolation and loneliness.

In 2016, Tivity Health established a Rural Aging Advisory Council composed of multiple stakeholder groups to address and advance partnership opportunities across the public-private lines. This group has played a key role in supporting solutions during the COVID-19 pandemic and also with other disasters, such as hurricanes, floods, and tornados.

Frequent Pulse Checks
Throughout the pandemic, Tivity Health has surveyed members to learn about their experiences and perceptions around a range of health topics, and how those have changed over time. These timely insights allow for greater empathy in communications while exposing unique challenges seniors are facing. Findings have been used to inform programming and have accelerated development to support members with challenges they are experiencing with nutrition, technology, and social isolation. We have also shared our data with strategic partners, clients, and policy makers to help advocate for our members well beyond our programming.

Transformation
Federal, state, and local response to the arrival and rapid spread of the coronavirus included widespread closures of businesses and stay-at-home guidelines. While there was little known about the virus, it became tragically clear that older adults are at greater risk of a serious illness and are safest if they remain at home. Tivity Health immediately began sending communications to participants to promote ways to stay active at home and to feel connected and engaged.
Within days, Tivity Health’s operating model was transformed from in-person, instructor-led classes to virtual fitness classes, led by our network of national trainers and many local instructors whom participants know and trust. Multiple classes per day are offered, which supports different time zones, fitness levels, preferences and language needs. Additionally, we expanded collaborations with our health plans to ensure seniors had nutritious meals. This was particularly important since our member surveys and health plan customers reported an increase in food insecurity early in the pandemic.

Collaboration and Partnership
Complex challenges, especially those caused by a sudden disaster, require collaboration across multiple organizations. Gathering insights, defining challenges and engaging with partners can result in greater creativity in problem solving and developing unique solutions. For example, member surveys and feedback from industry groups reinforced that many older adults were food insecure and in urgent need of nutrition assistance. Traditional safety net programs struggled to operate remotely, transform meal distribution programs and sourcing and faced unprecedented need levels. Through partnership with the National Association of Area Agencies on Aging (n4a) and the National Association of Nutrition and Aging Services Programs (NANASP), Tivity Health has provided member agencies with access to bulk shipments of Nutrisystem®, South Beach Diet® and Wisely Well™ healthy, frozen and shelf-stable meals. By quickly connecting available inventory with local agencies for distribution, this collaboration has supported the nutrition needs of thousands of seniors.

Summary
In short, disaster preparedness must include planning to serve frail and vulnerable populations. We must assure individuals that access to necessities will not only be provided but will also endure through a prolonged crisis. Trusted partners and established communications channels should be leveraged effectively to create solutions and make seniors aware of available resources. This approach has proven to be effective during the pandemic and should continue to be our approach as we enter new phases, such as the availability of vaccines. Connecting the right partners and channels will enable public health officials to increase utilization of the tools and resources available to mitigate the impact of the pandemic.

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World’s Leading Life Science Companies Now Enrolling COMMUNITY, a Global, Platform Trial for Hospitalized Patients with COVID-19

Three members of the COVID R&D Alliance - Amgen Inc. (NASDAQ: AMGN), Takeda Pharmaceutical Co. Ltd. (NYSE: TAK), and UCB (Euronext BR: UCB) - announced the first patient enrolled in the COMMUNITY Trial (COVID-19 Multiple Agents and Modulators Unified Industry Members). COMMUNITY is a randomized, double-blind, placebo-controlled, adaptive platform trial that enables an array of therapeutic candidates to be studied in hospitalized COVID-19 patients.

With worldwide COVID-19 deaths exceeding one million and a resurgence of cases globally, life science companies are working urgently to identify treatments that can potentially reduce clinical severity of COVID-19 in hospitalized patients. COMMUNITY is the first platform trial designed and launched by members of the COVID R&D Alliance, a group of more than 20 leading pharmaceutical and biotech companies who are devoting significant time, insights and company resources to speed the development of potential therapies, novel antibodies, and anti-viral therapies for COVID-19 and its related symptoms.

"As this insidious virus rapidly spreads around the globe," doctors need options to treat hospitalized patients who are actively sick and experiencing a range of symptoms as the disease progresses," said David M. Reese, M.D., Executive Vice President Research & Development, Amgen. "Working hand-in-hand with our peers, we hope to find options that could potentially save lives of the patients who will need treatments for COVID-19 before widespread availability of a vaccine."

COMMUNITY uses an adaptive design which allows for the addition, removal and simultaneous study of multiple therapeutic candidates during the course of the trial. Multiple candidates will be tested against a shared placebo-controlled arm. The design allows for a streamlined approach which may accelerate execution of the study and save time as we search for therapeutics in the fight against the pandemic. Immunomodulating therapies will be the first candidates to enter COMMUNITY. Other therapies may join in the future, such as antivirals.

The trial’s design and global footprint were selected to address potential barriers in the study of COVID-19 therapeutics. This includes anticipating and activating trial sites to align with the rise and fall of COVID cases across geographic regions as well as streamlining an influx in trial-related inquiries faced by some hospitals and health systems. COMMUNITY will onboard global sites in the United States, Brazil, Mexico, Russia, South Africa and other countries. This geographic diversity will allow the trial sites to be active when cases spike locally. COMMUNITY aims to simplify the study of investigational therapies that may result in potential treatment options and address the needs of hospitals in treating patients.

"COVID is not confined to one country, making it imperative that we share the challenges, successes and insights in real-time" said Dhavalkumar Patel, Executive Vice President and Chief Scientific Officer, UCB. “By sharing our expertise and resources, we hope to arm care teams with promising investigational therapies to help patients who cannot wait.”
Uncontrolled vascular and immune inflammatory responses have proven to be hallmark symptoms in patients facing severe COVID-19 infections. These patients may face increased risk of acute respiratory distress syndrome (ARDS), stroke and death. Initial therapies entering into COMMUNITY were selected based upon their potential to suppress or control the immune response or the resulting inflammation. None of these therapies have been approved by the FDA, EMA, or other health authorities for the treatment of COVID-19 or its symptoms and are still investigational. These include:

- Amgen’s OTEZLA® (apremilast), which may suppress immune response inflammation;
- Takeda’s investigational intravenous administration of lanadelumab, which modulates the kallikrein-kinin system and suppresses production of bradykinin, potentially lessening inflammation;
- UCB’s zilucoplan, an investigational medicine that may reduce overactivation of the immune system that contributes to ARDS.

OTEZLA entered COMMUNITY this week. It is expected lanadelumab and zilucoplan will enter in the coming weeks. Other anti-viral, immunomodulating and vascular agents may enter in the coming months.

COMMUNITY is studying hospitalized COVID-19 patients. This includes confirmed COVID-19 patients who may require either ongoing medical care, supplemental oxygen, noninvasive ventilation or high-flow oxygen devices, or invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). By enrolling both hospitalized Intensive Care Unit and non-Intensive Care Unit patients, the trial seeks to yield greater understanding of how therapeutic interventions may be used with hospitalized COVID-19 patients experiencing a range of symptoms.

About COMMUNITY

COMMUNITY is an adaptive, randomized, double-blind, placebo-controlled platform study designed to assess multiple candidates as a potential treatment for hospitalized patients with COVID-19, a disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV 2). The focus of the trial is to identify an effective treatment(s) for hospitalized COVID-19 patients, who are Grade 2 to Grade 5 on a Clinical Severity Status 8-Point Ordinal Scale.

The primary endpoint of COMMUNITY is time to confirmed clinical recovery without being re-hospitalized through Day 29 based on the clinical severity status scale, which is defined as achieving a score of 6, 7, or 8. Key secondary endpoints are oxygen-free recovery, improvement from baseline or fit for discharge from baseline, and all-cause mortality.

Patients will be randomized equally to either the candidate agent plus the standard of care or a placebo plus standard of care in a double-blind fashion. Patients who are randomized to placebo plus standard of care will be subsequently randomized equally to a matching placebo corresponding to an available agent.

About the COVID R&D Alliance

Organized in March 2020, the COVID R&D Alliance is operating unconstrained by past models of development and is accelerating the study candidates without regard to company affiliation. Members are sharing clinical trial data and real-world evidence, as well as crowd-sourcing early stage candidates to identify mechanisms and treatments that may be effective against COVID-19. Initial efforts by the group focus on advancing well understood therapies and late-stage investigational medicines for hospitalized patients who need treatment options. Activities are testing repurposed molecules and early stage candidates. Member companies have 40 trials expected to have findings in the coming months.

Additional information on the COVID R&D Alliance is available at www.CovidRDAlliance.com.
Vizient Sourcing Continuity Strategy

Mission Statement

Vizient’s Sourcing Continuity strategy exists to help Members Prepare, Respond and Recover to crises by creating technology-enabled services aimed at supply shortage Prediction, Prevention and Response.

Goals

I. Create and maintain a rapidly scalable crisis response capability:
   An escalating response system based upon the impact of the crisis.

II. Produce and refine supply shortage prevention programs:
   Programs aimed at helping members prevent shortages on key items through collaborations with distributors, manufacturers and technology providers.

III. Develop rapid, low-cost, alternative sourcing capabilities:
   Quick-action sourcing strategies aimed at securing product during a crisis.

Crisis Definition and Changing Member Needs

We define a supply chain crisis as any event that causes a disruption in any Member’s supply chain. This can include global pandemics (e.g., COVID-19, swine flu, SARS), acts of God (e.g., hurricanes, floods, earthquakes, wildfires) and other events (e.g., product recalls, regulatory changes).

In any crisis, Vizient member priorities change rapidly and migrate between a “normal” priority set, which is led by a desire for Vizient to provide certainty of contract value, and a “crisis” priority set, which is led by a desire for Vizient to provide certainty of supply. We call this the “crisis flip-flop.” All of Vizient’s Sourcing Continuity strategies are focused on being able to nimbly move between these priority sets in order to meet members at their various points of need.

MEMBER CORE PRIORITIES

Financial Value
We build tools and agreements that ensure best pricing and other value on supplies, services and pharmacy.

Certainty of Value
Inherent in sourcing ops and analytics is the longevity of created value.
Members can plan.

Reliability of Supply
In normal course of business this is a low concern — it is assumed.

MEMBER CRISIS PRIORITIES

Reliability of Supply
For shortage items, Members care most about availability solutions and less about financial value.

Certainty of PRICING
Even at higher rates, members are hungry for some ability to plan — even short term.

Financial Value
Becomes a secondary concern — it must not get in the way of Certainty of Supply.
Response Escalation Pathway and Capabilities

Vizient’s strategy centers around an escalating response structure based upon the severity, geography and overall impact of any crisis.

The Level 4 strategy focuses on the Prepare portion of our mission statement. Vizient continues to create tools and sourcing programs that allow us to monitor globally for crises in development and to help our members build stockpiles and alternative sourcing strategies that will help them respond to any crisis. Vizient has a dedicated team which stands ready to coordinate these activities.

Levels 3 through 1 focus on the Respond and Recover portion of our mission. In the midst of any crisis, Vizient stands-up tools focused on the crisis-affected regions and product categories.

These tools include:
- alternate supplier sourcing in which non-traditional or non-contracted sources of product are explored during shortages
- a steadily expanding team of sourcing experts to deal with member’s individual issues
- supply impact calculators and surge demand calculators for critical product
- regular communication of allocation and supply impact information
- activation of Novaplus Enhanced Supply stockpiles of critical products
- communication of emerging clinical and operational processes
- collaboration with local, state and federal government bodies
- coordination and distribution of large-scale donations

### LEVEL 1 — NATIONAL OR GLOBAL CRISIS

| Exec Council — COO | Nation-wide alt supplier sourcing, NEC activation, Clinical, Company-wide reporting, Govt interaction, donations | Expand 3 |

### LEVEL 2 — SIGNIFICANT REGIONALIZED EVENT(S) OR MASSIVE PRODUCT SHORTAGE

| Executive Council | Regionalized or PSC-wide – alt supplier sourcing, activate enhanced supply stockpiles, Potential clinical, Company-wide reporting | Expand 2 |

### LEVEL 3 — SINGLE OR MULTIPLE SMALL REGIONALIZED CRISSES (WILFIRES, STORMS, ETC.)

| DR leader | Regionalized solutions – alt supplier sourcing, activate enhanced supply stockpiles, calculator re-launch, regular reporting to leadership | Expand 1 |

### LEVEL 4 — NO IMMEDIATE CRISIS

| DR leader | NES, Shortage Reporting, Member Intake, Supply Issue Predictor | Static Team |
Healthcare Leadership Council Mission
Quality, Competition, Innovation

The Healthcare Leadership Council (HLC), a coalition of chief executives from all disciplines within American healthcare, is the exclusive forum for the nation’s healthcare leaders jointly to develop policies, plans and programs to achieve their vision of a 21st century system that makes affordable, high-quality care accessible to all Americans.

Members of HLC — hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, pharmacies, post-acute care providers, and information technology companies — envision a quality-driven healthcare system that fosters innovation. HLC members advocate measures to increase the cost-effectiveness of American healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to elevate value.

Providing access to health coverage for the uninsured, accelerating the growth of health information technology, and reforming healthcare payment systems to incentivize quality and positive patient outcomes are important HLC priorities, along with improving patient safety, addressing the healthcare workforce shortage, enacting medical liability reforms and developing patient privacy rules that protect confidentiality while enabling the necessary flow of information to healthcare professionals and medical researchers.

HLC shares its vision for quality healthcare with Congress, the administration, the media, the research community and the public through communications and educational programs. Because of the broad scope of HLC membership, HLC is well known by congressional members and staff as an integral source for comprehensive information on key health issues. HLC staff briefings and events such as the HLC Innovations health fair are well attended by members of Congress and staff alike.

And in the belief that healthcare is essentially local, HLC builds coalitions at the community level to pursue its goals for America’s patients. Six regionally based directors conduct activities with members of Congress, organize health briefings and forums to educate local media and the public, and form local health advisory committees to advocate for innovative, high-quality and affordable healthcare.