



SCOWCROFT INSTITUTE OF INTERNATIONAL AFFAIRS • 2024

SUMMARY OF CONCLUSIONS FROM HEALTHCARE COMMON OPERATING PICTURE AND HEALTHCARE DELIVERY WORKSHOP



TEXAS A&M UNIVERSITY
The Bush School
of Government & Public Service

Scowcroft Institute
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SUMMARY OF CONCLUSIONS FROM **HEALTHCARE COMMON OPERATING PICTURE AND HEALTHCARE DELIVERY WORKSHOP**

Scowcroft Institute of International Affairs • 2024

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EXECUTIVE SUMMARY

Mark Twain is credited with the quote "history doesn't repeat itself, but it rhymes." The world will face another pandemic or global emergency, and without deliberate action, our response will face similar core challenges. This report is intended to provide decision-makers in industry and government with additional data points to break this cycle and improve our nation's preparedness.

The Scowcroft Institute of International Affairs within the Bush School of Government and Public Service at Texas A&M University hosted a workshop in March 2024 with a variety of private sector and government experts to explore the experience of the healthcare industry during the COVID-19 pandemic and what policies are needed to better respond to future public health emergencies. The workshop included two panels, one focused on forming a healthcare common operating picture and the other on healthcare delivery.

Based on reviewing open-source information on lessons observed from the COVID-19 response, it is our opinion that there is a need for additional perspectives from the private sector. We are not aware

of a comprehensive U.S. Government (USG) after-action report review, although several federal agencies have published or documented COVID-19 lessons learned. The National Academy of Public Administration published a report in 2022 analyzing the strengths and vulnerabilities of the U.S. intergovernmental responses to the COVID-19 pandemic, but it focused in large part on the public sector response. Our series of workshops, this being the first, is an effort to enrich the library of lessons observed with knowledge from public-private partnerships and industry partners. We aim to support the public sector as we prepare for the future emergencies our nation will inevitably encounter.

This report generally presents opinions, observations, and insights shared by workshop participants with limited editorial input from the authors. However, the team has made the following recommendations based on their opinions, knowledge, and abilities in an effort to add additional intellectual rigor to the conversation.

Four recommendations emerged from observations shared in the workshop, summarized below.

Finding 1. Common Operating Picture

Recommendation 1: *The U.S. government should establish and sustain a framework for a Common Operating Picture (COP) with clear criteria for activation during emergencies. The COP would create a system for storing relevant emergency response data and sharing it between government agencies.*

Key Points:

- The government shouldn't run a constantly operating system with private sector data.
- A COP can focus on pre-defined data sets with clear rules for activation and deactivation.
- Test and exercise the COP to ensure functionality and allow decision-makers to practice using it.
- Collaboration with the private sector is crucial for defining key data elements.
- This framework would allow for data adjustments based on real-world situations.

Finding 2. Routine National, State, and Local Exercises

Recommendation 2: *The U.S. government should coordinate regular exercises of the national, state, and local responses to major health emergencies, such as pandemics, including tracking and implementing lessons learned.*

Key Points:

- Coordinated exercises are needed that simulate all-of-government responses to events like pandemics, happening regularly as part of a "battle rhythm."
- Exercises should occur at the national, state, and some local levels to test plans and assumptions.
- Exercises should go beyond theory and move past table-top discussions to include in-person role-playing and unexpected events to strengthen

decision-makers' mental resilience.

- Consider a large-scale capstone exercise with senior officials every 24 months, lasting at least 10 days.
- Build a learning framework that not only tracks lessons learned but also tracks their implementation. Request the Government Accountability Office (GAO) to issue routine reports to government departments and Congress reviewing and evaluating implementation of lessons learned, resource requests, and adherence to the exercise schedule.

Finding 3. Second-Order Effects on Preparedness Posture

Recommendation 3: *Government policies, like ripples in water, have far-reaching effects beyond their initial target. To improve outcomes, policymakers should consider these second-order consequences on the nation's preparedness posture.*

Key Points:

- Government policymakers should think critically to identify potential unintended consequences of policies that impact national preparedness.
- For example, the Make PPE in America Act aims to strengthen the U.S. supply chain for Personal Protective Equipment (PPE). However, waivers allowing full offshore production may be weakening domestic industry. To solve this issue, policymakers should carefully consider limited focused waivers to support U.S. manufacturers who can't get specific materials domestically, not just completely bypass them.

Finding 4. Coordinated, Layered Approach to Preparedness

Recommendation 4: *The U.S. government should pursue a layered and coordinated approach to improving preparedness involving extensive public-private partnership, government incentives, state-level collaboration, and improved supply chain management.*



Key Points:

- Provide government incentives:
 - Fund development of medical countermeasures (MCMs) with no commercial market.
 - Support a strong domestic pharmaceutical industry for MCM production.
- Promote state-level collaboration:
 - Facilitate ways to leverage state level standards for medical certifications across states.
 - Use compacts to promote the use of flexible standards to improve access to medical care in rural areas, potentially during emergencies.
- Improve supply chain management:
 - Recognize that just-in-time distribution is necessary for the efficiency of the healthcare system, but carve out exceptions for emergencies.
 - Leverage federal programs to incentivize hospitals to create limited supplies bubbles of critical Personal Protective Equipment (PPE).

This combined approach aims to leverage existing commercial systems while building preparedness through public-private partnerships. The goal is to be more efficient and effective in future emergencies.

These recommendations are intended to challenge the reader to consider more ambitious solutions to better prepare our nation for future pandemics and other health emergencies. Our team plans to conduct more workshops in this series, and we welcome suggested topic areas.

METHODOLOGY

The Scowcroft Institute of International Affairs hosted a workshop in Washington, DC in late March 2024 with a small group of stakeholders from across the U.S. Government (USG), academia, and private industry, many with firsthand experience in the healthcare sector during COVID-19. The purpose of the workshop was to analyze and provide observations on the COVID-19 response from an industry and academic perspective.

The workshop explored issues related to forming a Common Operating Picture (COP), medical supply chains, and healthcare delivery activities. The panelists were asked to identify the policy changes needed to better prepare for future emergencies and offer their opinions on how artificial intelligence could play a role in these efforts. The event was designed to promote interaction between the audience and panelists to foster more robust discussion and thinking.

The workshop discussion focused around two panels:

✓ **Common Healthcare Operating Panel:**

- ❖ Explore how industry supported an enhanced common operating picture during COVID-19 and how artificial intelligence could enhance the government's response to a future emergency or pandemic event.

✓ **Healthcare Delivery Panel:**

- ❖ Explore lessons learned from the hospital system, medical supply chain, and drug manufacturing industry during COVID-19 and how they anticipate artificial intelligence could play a role in future pandemics or other emergencies.

To promote open and honest discussion, the meeting was held under Chatham House Rule with an understanding that the names and affiliations of participants would not be made public.

This document presents a summary of the information and perspectives shared by workshop participants, including both panelists and audience members. It is intended to provide forward-looking insights to policymakers and industry leaders, especially in the

healthcare sector, about preparing for future health emergencies. All opinions expressed in this document represent the views of the authors, not any of the meeting participants, the Bush School of International Affairs, or Texas A&M University at large.

Summary of the panel participants:

✓ **Common Healthcare Operating Panel:**

❖ **Panel Members:**

- Professor, Texas A&M Health Science Center
- Chief Strategy Officer, Private Industry
- President, Private Industry

✓ **Healthcare Delivery Panel:**

❖ **Panel Members:**

- Executive Director, National Association
- Chief Executive Officer, Private Industry
- Chief Medical Officer, Not-for-Profit
- Chairman, National Coalition

The audience was composed of a diverse set of government and private industry representatives. USG participants included agency program officials from the Department of Health and Human Services, the Department of Veterans Affairs, and the Department of Homeland Security. Private sector participants included representatives from small start-ups and larger companies with backgrounds in biotechnology, healthcare technology, legal/policy practice, and the medical countermeasures industry.

INTRODUCTION

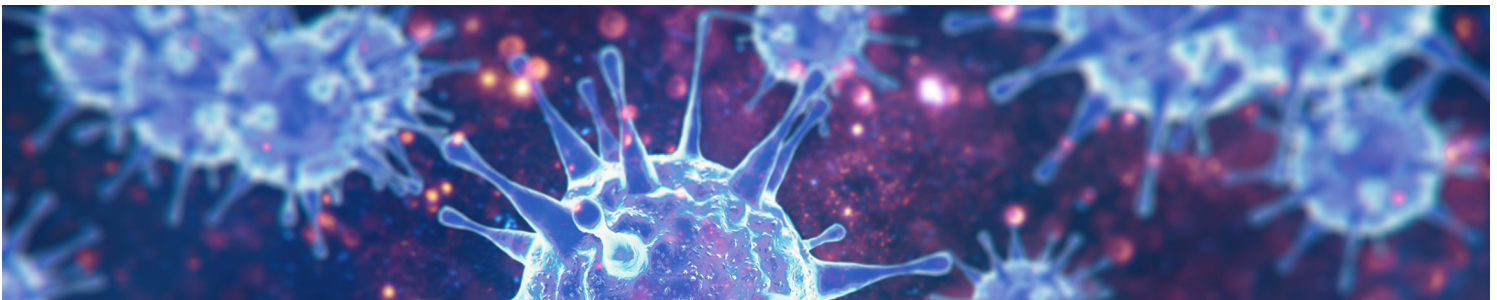
Since the publication of the 2005/2006 national strategy, the Swiss Cheese Model has informed our nation's approach to pandemic preparedness (Biomedical Advanced Research and Development Agency, n.d.). In this model, each defense or preparedness measure has weaknesses or "holes." No single measure can solve every challenge or provide a robust defense on its own. However, many defensive layers offer much better protection. Like a stack of Swiss cheese slices, each layer covers the holes in the layer above and below it, reducing vulnerabilities. In the case of pandemic preparedness, this describes the federal government's goal to create an integrated, scalable approach that reinforces local healthcare systems.

The federal government's Emergency Support Function 8 (ESF-8) Medical Capability Allocation and Reallocation Council (Council) evaluates requests for high-demand, and limited, federal medical resources. The Council coordinates federal medical assistance to supplement State, Tribal, Territorial, and Local (STTL) medical resources based on validated requirements in support of major disaster events (e.g., pandemics, natural disasters, domestic terrorist attack). During the COVID-19 response the ESF-8 Council was under the leadership of the Assistant Secretary for Preparedness and Response (ASPR) in the Department of Health and Human Services (HHS) in partnership with the Federal Emergency Management Agency (FEMA), which plays a critical role in all aspects of emergency preparedness in the United States. FEMA leveraged its existing partnerships with State and local governments to provide guidance, technical assistance, and financial support to the ESF-8 team. Reliable and rapidly available data was critical for using objective criteria to make resource allocation decisions.

The Emergency Support Functions (ESFs)

The ESFs integrate governmental and certain private sector capabilities into an organizational structure that provides support, resources, program implementation, and services to save lives, protect property and the environment, restore essential services and critical infrastructure, and help victims and communities return to normal after an emergency.

- ESF-8, "Public Health and Medical Services," provides the mechanism for coordinated Federal assistance to supplement state, tribal, territorial, and local resources in response to potential, actual, or developing public health and medical emergencies.
- The Department of Defense, Department of Veterans Affairs, the Public Health Service, and HHS Administration for Strategic Preparedness and Response provided medical forces to respond to state requests for support during the COVID-19 pandemic. Each agency has its own authority, but it was quickly recognized that a body was needed to coordinate the response across agencies and departments, resulting in the creation of the ESF-8 Council.





FORMING A HEALTHCARE COMMON OPERATING PICTURE (COP): DATA-DRIVEN SUPPORT FOR RESOURCE ALLOCATION

The ESF-8 Council, HHS, and partner agencies recognized early in the COVID-19 pandemic that data, particularly a Common Operating Picture (COP) of data, would provide valuable assistance to federal decision makers working on the whole-of-government response. In April 2020, ESF-8 began the design of a data dashboard under the name HHS Protect. Working with private companies, specifically TeleTracking, ESF-8 implemented

a more robust public-private partnership COP. The ability of HHS to quickly contract for this tool was crucial to its success. The COP provided a central hub to collect, integrate, and share COVID-19 data in real-time across federal agencies and with state, local, territorial, and tribal partners, allowing decision-makers to better allocate scarce medical resources.

Why A Common Operating Picture?

The onset of the COVID-19 pandemic created an immediate need for data to enhance the national ESF-8 medical response and facilitate a more efficient allocation of high demand, low density medical capabilities. This resulted in a framework designed to support the ESF-8 Council as a data-driven organization. Data included actual hospital data to make decisions about requests for support by, for example, communities experiencing a spike in COVID-19 cases. It later expanded to include supply chain information, providing visibility related to operational needs. A requirement to sustain a framework of this nature after the pandemic could support exercise planning and future emergency responses.

Discussion: During the initial wave of COVID-19 infections, models were less capable at predicting disease spread. A data matrix evolved into a Common Operating Picture (COP), allowing for enhanced decision making as knowledge about the outbreak and the disease itself evolved on an almost daily basis.

ESF-8 envisioned a COP with centralized data to improve medical response support options and allocate finite resources.

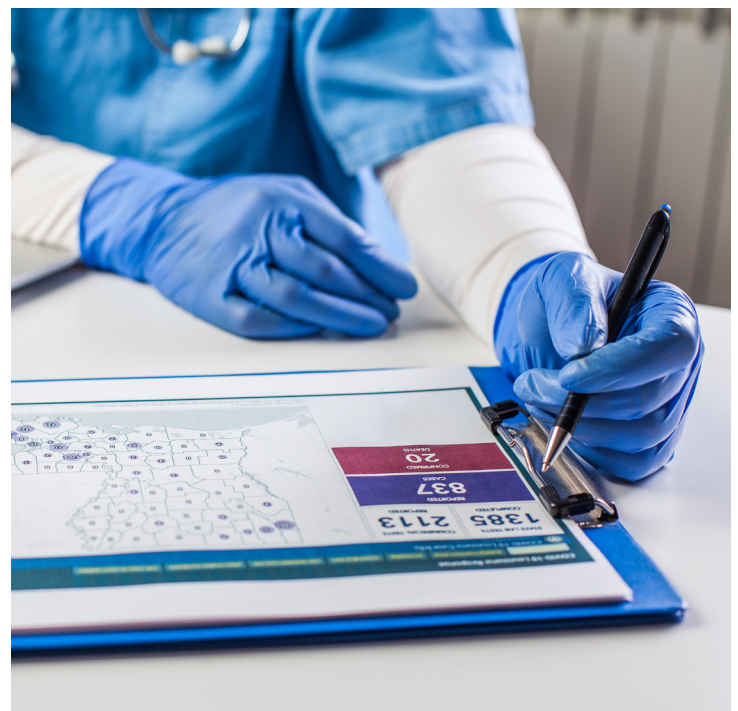
The initial system was designed to assess needs and capability requirements by analyzing the risk in a particular location in terms of threats and vulnerabilities. Threats included data related to spread factors and infection rates. Vulnerabilities included data on health system infrastructure, such as ICU beds, ventilators, etc.

In the early summer of 2020, ESF-8 expanded its COP with the HHS Protect and TeleTracking database to enhance its initial dashboard. This and further upgrades improved operational response options.

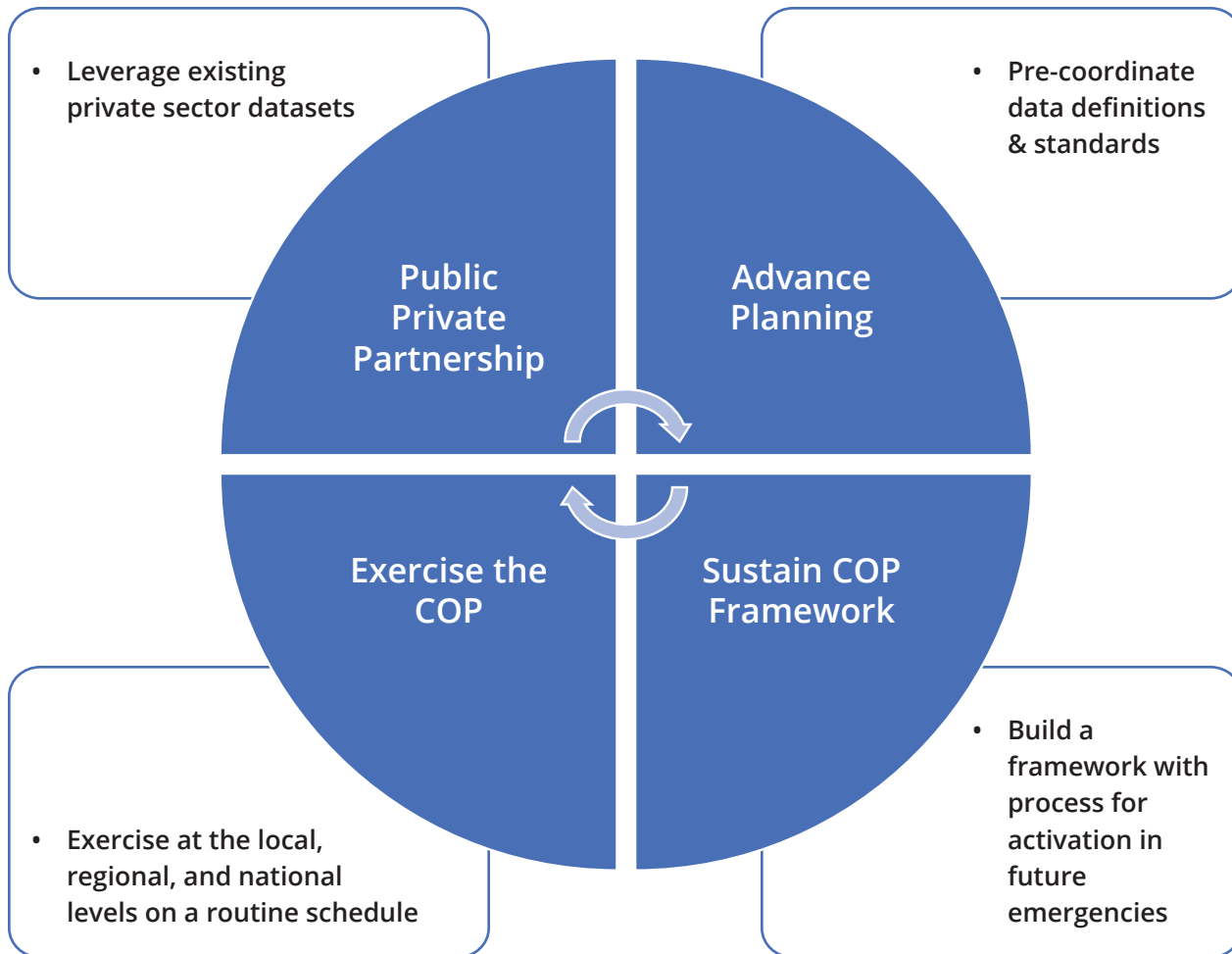
In the workshop, the panelists and audience members explored lessons learned and shared observations from the private sector, academia, and government. Discussions centered on how the COP enhanced decision-makers' abilities to allocate resources and how such a tool could be positioned for future emergencies.

“If we had set forward a project to do what we did in a matter of weeks, maybe a month and a half, I think it would have taken a decade. But under crisis we were able to bring people together, not just as a technology platform.”

– Panel Member Comment



Common Operating Picture (COP) Summary of Observations and Lessons Learned



One objective of the COP was to eliminate the need to pick up the phone to determine the availability of hospital beds, medical supplies, and other resources in impacted communities. Going forward, it was recognized a need exists to ensure a methodology or framework is in place prior to an event. Immediate access to a handful of data points can provide future decision-makers with a picture of key factors like number and type of hospital beds available, count of specific disease patients (e.g. COVID-19), patients under investigation, therapeutics or vaccines on hand, and status of critical supplies, allowing decision-makers to better assist local communities from day one. The initial framework was created in days, although data elements only became usable within a couple of weeks, with further buildout occurring over

the next several months. The ESF-8 team did not wait for perfection to begin using the tool.

“We had people engaged at every state level. We had people engaged with HHS, with ASPR, CDC, FEMA, etc. And when you got around that table nobody had a jersey.”

– Panel Member Comment

Summary of the Discussion

The following is a summary table of the observations and lessons learned related to the four major parts of the COP discussion from the panel and audience.

Advance Planning

- Systems in place must be able to scale to the problem at hand.
- Certain emergencies require data on what is happening in real time.
- Real-time private sector data on patients, staff, beds, etc., provides a site picture at the local level.
- National-level decision-makers need greater real-time ability to roll-up or add data sets to enhance national or regional responses based on the emergency.
- Systems must be driven by trust, which requires transparency. The government needs to say, "here's what we're doing with your data. And this is why. And this is how we're protecting you."
- The system should be based on confidentiality with de-identified patient information.

Sustain COP Framework

- Private sector suppliers and medical systems have economic incentives not to share internal data due to competitive and reputational concerns.
- During the COVID-19 pandemic, the COP provided data on bed availability and utilization across thousands of sites with routine updates.
- The framework should leverage existing private sector data to avoid starting from scratch.
- The framework should leverage Health Information Exchanges, especially those with more advanced data systems, privacy protections, and data management.

Exercise the COP

- Responsible agents should be identified to coordinate system access for exercises at local, regional and national levels.
- Exercises should test the ability to enhance daily decisions, like where to allocate medical support or other resources to assist local and state healthcare systems.
- Data visibility is a critical part of any exercise mechanism or framework, but it is not the only element.
- Exercises should include using the framework to distribute vaccines and therapeutics to identify limitations and lessons learned to improve future responses.
- Decision-makers should track lessons learned to ensure implementation.

Public-Private Partnership

- Collaboration between public and private sectors is key to improving the ability to respond.
- Government agencies are intended to track private sector hospital beds or medical supplies.
- The response moved from no data to more data and eventually a greater ability to leverage government and private sector data sets in the COP.



- Establish in advance a mechanism to address private sector concerns with sharing internal data from proprietary systems prior to and after the emergency.
- The Public-Private Partnership model worked during COVID-19 but could be improved.

“If you don't have common language, if you don't have common definitions and don't have people agreeing to it in a widespread way, it's all a Tower of Babel.”

– Panel Member Comment

The pandemic emphasized the need for flexibility and redundancy in healthcare systems to address all-hazards emergencies effectively. An audience member shared how the government and healthcare industry should

consider taking a step back and look at the broader perspective. He challenged the group to build solutions to challenges based on successful models from other sectors. Specifically, one should:

- Break down the problems into a set of smaller problems or modules.
- Explore solutions to analogous problems in other industries.
- Identify and test new solutions from across industry sectors.

The following is a summary of consensus observations expressed by the panel or audience related to potential future policies.

1. Common Language and Data Authentication:

- Advance planning of common language and definitions, such as defining what constitutes a "bed," is crucial for interoperability in an emergency.
- Authentication mechanisms to verify data sources ensure data accuracy.

2. Lessons from Industry & Privacy:

- Leveraging industry experiences, particularly with open standards and open-source software can provide insights on how to drive industry-wide improvements
- Public trust and privacy are key to public-private governance and transparent data sharing mechanisms within or outside of the various Health Information Exchanges (HIEs).

3. Narrow Standards & Proprietary Practices:

- Narrow standards can lead to proprietary industry practices, hindering interoperability and innovation.
- Comprehensive standards that are tested in advance can foster collaboration.

4. Bridging Gaps:

- The government can help bridge gaps between industry sectors. For example, it can foster cooperation and help solve challenges with data formats, protocols, privacy, transparency by using incentives and policy.

5. Leverage Healthcare Data Standards:

- Initiatives like FHIR (Fast Healthcare Interoperability Resources) could serve as a tools to facilitate more standard data definitions.

6. Health Information Exchanges (HIEs):

- HIEs contain valuable operational and clinical data, which could enhance the response picture for decision-makers during an emergency.
- It was generally agreed that HIE data was underutilized during the pandemic response.

7. Operational Data vs. Predictive Data:

- Operational data, providing real-time insights, was more accurate and actionable than predictive data during COVID-19.
- Predictable analysis tools can improve adaptability and responsiveness to changing environments in a future emergency.

8. Adapting Artificial Intelligence (AI):

- AI algorithms need to be continually updated, trained, and adapted to live data to maintain accuracy and relevance, particularly in dynamic situations.
- Situational awareness is the key need during an emergency response.

9. Collaboration and Adaptability:

- Collaboration across sectors should be a part of standard operating procedures for emergency response.
- Adaptability to evolving circumstances is essential in any effective response



Data Protection and Additional Conclusions

The discussion covered how the protection of data in the healthcare sector is essential. A balance of protections is required in any data platform, especially for unpredictable and broad events like bioterrorism or natural disasters. It was generally accepted the government needs general principles to balance hospital needs, interests of vendors with proprietary data, and response requirements during an emergency.

A standing COP framework with shared standards and criteria to activate in certain emergencies has the potential for augmentation with AI. The discussion noted several advantages and disadvantages of using AI. One participant shared that if significant data was available, it might help uncovering hidden correlations to assist federal, state, and local decision makers. However, the speed of early events typically limits the amount of available data; thus, while AI should be considered it must not be viewed as infallible, especially before large datasets become available. AI integrations should be transparent and exercised to explore limitations and strengths prior to the event to build and sustain trust with the public. The importance of clearly defining a COP framework with a focus on how to maximize the positive impact on healthcare outcomes and minimizing proprietary data access was a key observation.

Overall, the discussion underscored the importance of leveraging existing resources, establishing robust standards, and fostering collaboration to address future healthcare challenges effectively.

Furthermore, the panel members noted a need for the government to share lessons learned from military medicine, federal, and local response efforts.

Overall, it emerged that addressing cultural barriers, promoting automation, and leveraging more real-time data visibility are crucial for enhancing healthcare system resilience and response capabilities in future emergencies. Specifically, a need exists for more innovative thinking, collaboration across sectors, and a proactive approach to healthcare system challenges, with a focus on leveraging lessons learned from the pandemic. Future solutions should address policy hurdles to enhancing effective decision-making, including market competition and reluctance to share data among the public and private sectors.

There was consensus that, due to connections

HIE Deep Dive Comments

- Healthcare Information Exchanges (HIEs) allow healthcare providers to securely access and share information about patients electronically.
- HIEs vary in robustness across states.
- Decision-makers should identify and address barriers to HIE data sharing, like how payment information can disincentivize participation.
- Integration challenges with long-established practices often limit true data exchange and result in PDF delivery that hinders automation and data collection efforts.
- Distinctions between operational and clinical data underscore the need for interoperability.
- Few systems have truly effective logistics management capabilities.
- Opportunities exist to improve interconnectivity and automated collection of logistical and clinical data. Government policies can encourage making these improvements to empower a future crisis response.

between healthcare and broader societal and security concerns, the information shared and lessons learned should inform not only healthcare policy, but economic and national security policy as well. The conversation underscored the importance of leveraging existing infrastructure, investing in early warning systems, and embracing innovation to improve preparedness and response in the healthcare sector and beyond.



HEALTHCARE DELIVERY: HOSPITAL SYSTEM, MEDICAL SUPPLY CHAIN AND DRUG MANUFACTURING OBSERVATIONS AND LESSONS LEARNED

Background

The ESF-8 Council, HHS, and partner agencies recognized early in the response that supporting the entire healthcare delivery system was critical for an emergency at the scale of a pandemic, which necessarily involves the whole nation or world. This holistic view of the healthcare system encompassed providers, support staff, hospitals, supply chain, logistics, manufacturing, and core raw materials.

In hindsight, it is always easier to look back as a critic. This discussion attempted to reflect on what was known at the time, and the system's response as the threat, knowledge, and environment evolved during the COVID-19 pandemic. That said, it is impossible to completely avoid hindsight bias, and reflections on the pandemic offered by meeting participants were likely influenced by the present-day environment.

Many of the themes raised in this discussion paralleled those in the first panel—both addressed how federal and private-sector actors worked to enhance visibility and make better decisions under uncertain, rapidly changing conditions during the pandemic. Throughout the discussion, panelists and audience members shared thoughts on how to improve operations in future emergencies.

In early 2020, ESF-8 partnered to expand and support healthcare delivery on many fronts.

For example:

- ESF-8, ASPR, and FEMA leveraged relationships with healthcare associations to share educational material and collect information on health care challenges.



- ESF-8 established a framework for a program, now called Operation Warp Speed, to leverage industry partners by providing federal support to de-risk, jump start, and accelerate the development and production of vaccines and therapeutics for the COVID-19 response. The design was based on the principle of parallelization, rather than following the standard serial development pathway, without omitting any safety or scientific steps. For example, in normal times, a drug developer will not produce doses for the phase three clinical trial until the phase two data is analyzed. In this case, the government de-risked industry investment by funding advanced manufacturing before the release of phase two data to accelerate the deployment if products met the required scientific threshold.
- States and the private sector responded to the pandemic with process and system adjustments. States are responsible for determining who medical practitioners are and how they practice within their borders, thus the requirement for state licenses to practice medicine. The states quickly allowed cross border medical practice as they allowed medical staff with licenses from other states to practice in their state without additional hurdles. This facilitated maximum flexibility by allowing licensed medical staff to more easily travel to where they were needed.
- The private sector response included hospitals pausing non-critical medical (or elective procedures) to reduce potential additional infections and create more capacity within the healthcare system. Many believe these steps significantly increased the number of medical providers who could shift into other critical care lines of effort at the onset of the pandemic.

Partnerships across the healthcare enterprise were sometimes facilitated by federal, state, or local policymakers. In other cases, they formed as a natural response by individual private or public decision-makers based on the observed, projected, or perceived impacts of the COVID-19 pandemic.

COP Impact on Healthcare Delivery

It was noted during this second panel how the public-private partnership behind the COP assisted decision-makers' abilities to allocate resources within the healthcare enterprise.

At the federal level, it was noted how the data allowed for more informed decisions about how to deploy resources and distribute vaccines and therapeutics. The panelists and audience identified the interconnectedness of the two panel discussion topics.

Observations on Healthcare Delivery from Private Industry and Academia

The second panel explored lessons learned and observations from the private sector and academia related to healthcare delivery during the COVID-19 response, with the aim of providing information to policymakers about how to improve future responses. Audience members, including government officials and other industry leaders, provided additional insights and questions.

Collaboration between industry and the public sector, as well as various non-governmental organizations, was seen as key to solving operational challenges more effectively.

Participants also observed that the urgency of the crisis facilitated rapid problem-solving and collaboration, knocking down barriers that would have otherwise taken years to overcome. As the pandemic has subsided, participants noted that the capabilities and frameworks developed during the crisis have diminished or not been sustained. This highlights the need to continue investing in preparedness. The discussion also explored strategies to improve preparedness for future pandemics and other health emergencies.

Future Pandemic Healthcare Delivery Preparedness Observations **Public-Private Partnerships for Medical Counter Measures (MCMs)**

The government serves a crucial role in incentivizing companies to develop medical countermeasures (MCMs), since there is often no commercial market for such products. Public-private partnerships are essential for clarifying needs, providing certainty, and creating a viable business case for companies to invest in providing MCMs.

Project BioShield Act

The objective of Project BioShield is to accelerate the research, development, procurement, and availability of effective medical countermeasures against Chemical, Biological, Radiological, and Nuclear (CBRN) threats.

Project BioShield was created in 2004 as P.L. 108-276, to encourage the private sector to develop medical countermeasures with a novel mechanism for federal acquisition of those newly developed countermeasures.

It was originally funded at \$5.6 billion for 10 years to support companies in developing and supplying products. Today, funds to implement Project BioShield activities are provided to BARDA on a yearly basis through annual appropriations. The initial appropriation successfully generated private sector investment in and production of medical products needed to address the highest priority threats (e.g., smallpox, anthrax, radiological).

Project BioShield also authorizes the Food and Drug Administration to grant Emergency Use Authorizations (EUAs) for medical countermeasures following a public health emergency declaration by the Secretary of Health and Human Services (HHS) based on either the HHS Secretary's determination of a public health emergency with the significant potential to affect national security or on a determination of heightened risk of a CBRN attack on the public or U.S. military forces (made by the Secretary of Homeland Security or the Secretary of Defense, respectively).

Source: <https://medicalcountermeasures.gov/barda/cbrn/project-bioshield/>

A strong relationship between the pharmaceutical industry and the Administration for Strategic Preparedness and Response (ASPR) is needed to support advanced research and development of lifesaving MCMs for emergencies.

Project BioShield provided a foundation not only for ESF-8 but for relationships with industry. These mechanisms created relationships that were leveraged to great effect during the pandemic response.

The United States faces real, pressing Chemical, Biological, Radiological, and Nuclear (CBRN) threats in addition to the threat of natural or man-made infectious diseases. The past few decades have seen biological terrorism, the use of chemical weapons, and escalating threats of nuclear weapons use. The common understanding that state and non-state adversaries are willing to develop and use biological weapons illustrates the risk that these weapons pose to U.S. interests and the homeland. We must be prepared to respond to these threats.

ASPR has a goal to make at least one countermeasure available for all CBRN material threats. The following figure from [MedicalCountermeasures.gov](https://medicalcountermeasures.gov) describes ASPR's approach:

The panel noted that U.S. government investments in MCMs should consider several key characteristics:

- Typically, it requires 10 years to develop a countermeasure for approval.
 - This assumes that the basic science is advanced to a point that allows for development.
- Long-term financial investment to develop new drugs, vaccines, or other MCMs are often riskier than investments in other products due to scientific and regulatory complexities.
- Programs like Project BioShield need consistent inflation-adjusted federal support to allow the enterprise to develop and evolve.
 - Given that there is little-to-no market demand for these types of MCMs, if not for federal investments, few companies would participate in the MCM development ecosystem.
 - As threats continue to advance and emerge, existing partnerships can be leveraged to take advantage of new scientific opportunities to reduce our nation's risk in these areas.
- The moderator noted that we may need to consider alternative funding mechanisms to



Source: <https://medicalcountermeasures.gov/barda/cbrn>

stabilize federal investment. For example, in addition to traditional annual appropriations, could there be a public good user fee.

- Promoting MCM public-private partnerships creates a sense of urgency to prepare for emergencies. These programs are critical to ensure the United States is developing, building, and maintaining the diagnostics, therapeutics, and vaccines needed for future emergencies.

Traditionally, companies are hesitant to assume financial risks for products without an existing commercial market due to the sequential nature of development, validation, and manufacturing. During the COVID-19 pandemic, the government took on this risk to increase investment and accelerate development timelines. However, in certain emergencies, even waiting 6, 9, 12, or 18 months for treatment options could result in massive negative impacts on society and the economy. Participants expressed a need for the United States to allow companies to move forward more swiftly in the MCM space.

Allocation of Scarce Healthcare Resources

The panel highlighted that the healthcare delivery market is not a free market given the federal government's significant role in price-setting and incentive programs; however, participants also noted that it still allocates resources using a market-based system. Panelists emphasized that both ethics and public understanding pose significant challenges when allocating scarce resources.

During the pandemic response, the government had to develop clear, fair, and comprehensible criteria to allocate scarce resources, including manpower and products donated by pharmaceutical companies, in support of local communities.

Factors to consider when allocating scarce therapeutics, vaccines, and other resources:

Consistent, Fair, and Explainable Criteria

- Allocation must include all states, tribes, and territories.
- Criteria should provide a fundamental sense of fairness.



- Localities and the health care industry could accept scarcity as long as they felt that everyone in the United States was treated in an equitable manner.
- Ensure people understood the scarcity conditions.

Principles of Fairness

- Geographic Equity: ensure that no one region or area receives preferential treatment solely based on their location.
- Temporal Equity: recognize that individuals affected by disease at different times during an outbreak are equally deserving of treatment and carefully consider how to allocate resources over time to avoid favoring one time over another.

Timing

- Federal policymakers must appreciate production schedules as manufacturers do not produce or deliver products all at once.
- Press releases should set expectations for communities and the healthcare delivery system without clearly denoting delivery dates.

Repeatable

- Decision making should be based on reliable, frequently updated, shareable, and broad data.
- Decision-makers must recognize that distributing medical products is viewed as a net public good by industry and communities.

It was noted that the public accepted the allocation of scarce resources if they perceived the decision-making process and distribution system as fair, equitable, and transparent.

More Resilient, Diverse, and Secure Medical Supply Chains

Consensus was readily achieved on the necessity of advance planning to set equitable criteria before making distribution decisions, even in the private sector. It was emphasized how private sector vendors prioritized distribution to healthcare entities based on their historical

Strategic National Stockpile

The Strategic National Stockpile (SNS), established in 1999, held about \$8 billion in assets prior to the COVID-19 pandemic.

The SNS was not designed or funded to serve as a supply house for the whole nation, rather it was intended to support a regional disaster response until the community can recover or prepare for CBRN events requiring MCMs not available to the public at large.

In 2002, Congress expanded the SNS's mission from holding vaccines and antidotes to responding to biological or chemical events. Over time the mission grew "to provide for the emergency health security of the United States... in the event of a bioterrorist attack or other public health emergency."

In 2020, before the COVID-19 pandemic, the Congressional Research Service (CRS) identified that the SNS had inventory of 38 drugs and 44 medical supplies.

The SNS's mission of responding to CBRN events was further expanded to a broader all-hazards focus. The SNS mission now covers events like hurricanes, fires, and natural pandemics. It is not clear that the items in the stockpile or its base funding is aligned to this expanded mission. In theory, Congress has provided annual funding to purchase new products and replace expiring stocks.

If funding does not support the mission, then the program must triage and leave some components incomplete.

The 2020 CRS report identified that since the SNS's initial funding, its annual budget has rarely exceeded \$700 million. Most years, it was funded at less than \$600 million.

Source: <https://s3.us-west-2.amazonaws.com/napa-2021/Build-More-Resilient-Diverse-and-Secure-Supply-Chains-Article-4.14.2021-Bartrum-002.pdf> (Reproduced in-part with approval from author).

purchasing patterns and order volumes, raising questions about fairness and equitable access to supplies. During the COVID-19 pandemic, non-typical buyers, like nursing homes, required significant quantities of personal protection equipment despite low order volume during normal times. The discussion noted that some non-typical or smaller customers struggled to obtain needed supplies.

The response highlighted challenges at healthcare facilities with cold chain storage capacity, workforce availability for vaccine administration, and acquiring necessary equipment amidst high demand and supply chain disruptions.

Advanced visibility into supply chain dynamics, including utilization rates of medical supplies, was needed during the response to ensure effective distribution and allocation of resources. It may also be necessary to reduce reliance on prime vendors. Advance planning could consider mechanisms to better align supply volumes to organizations based on actual utilization needs during an emergency.

The following key points were made about medical supply chains:

- The **Strategic National Stockpile** was noted as not having the required supplies for the COVID-19 pandemic response, and some supplies were out of date. It was unclear if recipients were aware of the SNS's participation in the Food and Drug Administration (FDA) product extension program.

Many outside the biomedical or medical logistics industry may not be aware that the FDA is the federal agency responsible for ensuring the safety and effectiveness of medical products. The FDA has a critical role in overseeing aspects of the U.S. medical product supply chain.¹

- **Gray Market Manufacturers:** An unintended consequence of broadly applying the Emergency Use Authority was to create an opportunity for more gray

market manufacturers to move into the supply chain.

- **Supply Chain Visibility:** A need was noted to expand visibility across the medical supply chain and upstream of it. Questions that should be considered in a future COP included:
 - Are the items on-hand?
 - What is the definition of utilization?
 - What supplies are gray market?
 - How many supplies are already held in the hospital system?
- **Rural Hospitals and Medical Supplies Allocation:** Audience members noted concerns with the allocation of medical supplies by industry based on prior usage. It was acknowledged that although the federal role was likely limited outside of a crisis, the government could facilitate better advance planning with industry to improve the allocation method. One suggestion was for an association like the American Hospital Association to lead a review on how well the current private sector allocation supports a sense of fairness and equitability across the healthcare market that may result in a voluntary revision for the allocation process. Specifically, it noted that rural hospitals that may have a smaller historical purchase volume compared to urban or larger hospital groups could have been negatively impacted during the COVID-19 pandemic.

“Distributors really have no accurate visibility into what true utilization is, because... hospitals [are] building inventory reserves so that they don't run into the situation where they don't have the supplies.”

– Panel Member Comment

Participants explored ways to ensure hospital efficiency and supply levels are balanced for effectiveness in a

¹For more detail on the FDA's role in supply chain, see Congressional Research Service report R46507, published Sept 1, 2020: <https://crsreports.congress.gov/product/pdf/R/R46507>

just-in-time stock system. The discussion also covered policy mechanisms to promote limited supply bubbles at hospitals in a potential future emergency with support from CMS facility cost structure.

The audience and panelists discussed how technologies

like blockchain combined with Radio Frequency Identification (RFID) can reduce gray market ambiguity. The table below was taken from a National Academy of Public Administration article mentioned at the event and referenced above.

Summary Matrix of Policy Recommendations to Build a More Resilient, Diverse, and Secure Supply Chains

Enhancement	Overview	Who would Oversee	Impact
Hospital Level Emergency Response Limited PPE Supply Bubble Policy	Limited to handful of PPE supply items, such as: Gloves, Coveralls, Gowns, Surgical Cap, Head Cover, Shoe Covers, Eye Protection, Face Shield, Mask, Respirator, Hand Sanitizer, Thermometer, Biohazard Bag, Specimen Swab, Transport Medium, Viral Transport Kit, and Human Remains Pouch.	U.S. Centers for Medicare & Medicaid Services (CMS) hospital accreditation process.	Ability to reduce the immediate resupply requests, provide distributors and manufacturers the ability to respond and rebalance capacity while it preserves the hospital industry's ability to use "just-in-time" or other cost management systems.
RFID Blockchain system on the PPE Supply Integrity	Develop industry standards that could be incorporated into government PPE procurement efforts to facilitate the RFID and blockchain security systems to enhance the integrity of the supply chain.	Industry in partnership with government procurement policies.	Creates a unique tracking system to eliminate or significantly reduce gray market PPE from entering the hospital system, speed up the validity and legitimacy of the product for the business enterprise.
Working Capital Fund (WCF) for the Strategic National Stockpile (SNS)	Congress to provide the SNS with a WCF to allow the SNS to have a tool to support full-cost recovery and lower operational risk and replenishment cost of supplies like PPE.	The Strategic National Stockpile (SNS) leadership and Department of Health & Human Services (HHS).	A WCF in the SNS can increase cost transparency, efficiency, and improve mission operational success with resources better aligned to requirements to drive proactive customer engagement, detailed cost analysis, and informed demand forecasting.

Source: <https://s3.us-west-2.amazonaws.com/napa-2021/Build-More-Resilient-Diverse-and-Secure-Supply-Chains-Article-4.14.2021-Bartrum-002.pdf>

Political Will to Execute Lessons Learned and Policies

A consensus observation was that once the government moves through an emergency it often lacks the willpower to fully execute or follow-through on lessons learned. It was noted how support flags as the event falls farther into the rearview mirror. A White House, Congress, or both will move past the event to focus on the next crisis and fail to spend political capital to secure the funds, policies, or laws required to better handle future emergencies of the same kind.

For example, the long-time support for Project BioShield apparent on Capitol Hill does not necessarily translate into resource allocation in the budget request from the Office of Management and Budget as they build a President's budget or at the Appropriations Committees in Congress that struggle with allocating limited federal funding. Specific challenges noted included:

- **Moving Beyond Crisis Response:** The historical pattern of temporary solutions, like those seen with Ebola, avian influenza, Zika, and now COVID-19 needs to shift toward longer-term sustained support of policies, investment, and capability growth for future emergencies.
- **No Secondary Market for MCMs:** The absence of a secondary market for MCMs highlights the need to create incentives for sustained industry engagement.
- **International Needs:** The pandemic has highlighted the preparedness needs of other countries. The U.S. government could support a secondary market for MCM by leveraging U.S. investments with partner country contracts or using the foreign military sales program to further build global resiliency for allies.

“Organizations have three basic levers—increase revenue, decrease costs, and change the process—the most overlooked is the third.”

– Panel Member Comment

The discussion highlighted the need for advanced and sustained investment, international collaboration, and innovative funding mechanisms to address current challenges and ensure preparedness for future health emergencies.

Scale and Workforce Challenges

Despite preparation, the demands on the healthcare industry and medical supply chain during the pandemic exceeded expectations. This included both the quantity of doses needed and the workforce required to meet production demands. It was noted that during previous advance planning exercises, few participants fully understood the impact of potential workforce shortages, alongside the lack of facilities, raw materials, and production tools. If unaddressed, these combined challenges will continue to hamper future responses.

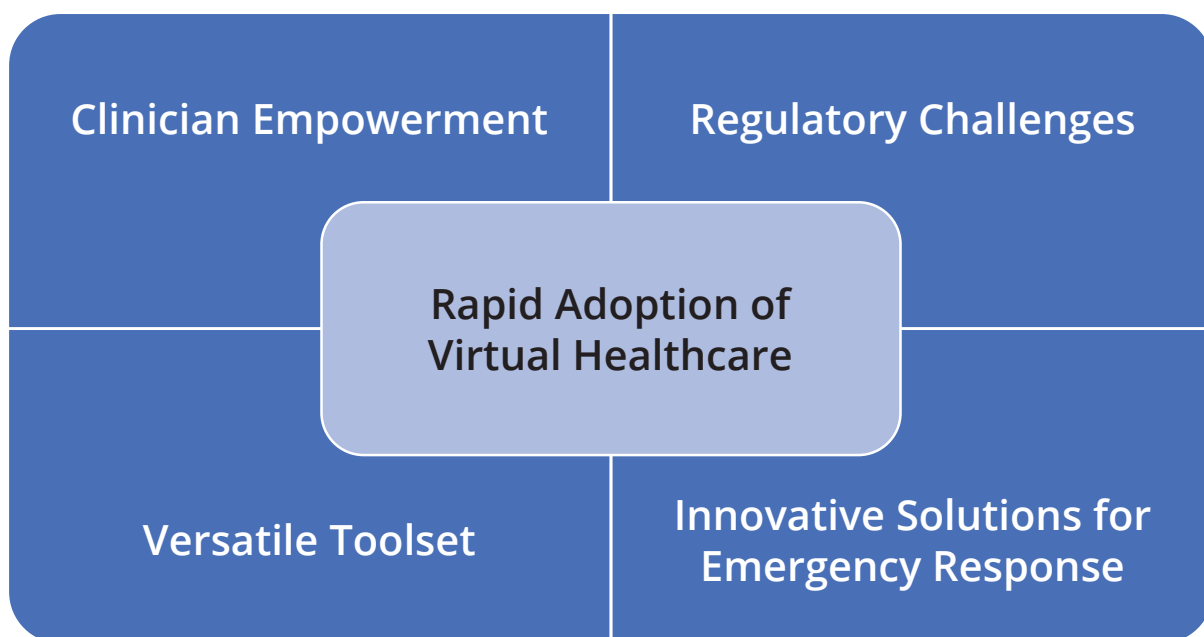
Healthcare Delivery – Virtual Healthcare Revolution of COVID-19

One positive from the pandemic was more widespread adoption of virtual health care. Post-pandemic, the trend appears to have continued, though at a lower rate.

A number of questions were raised about how to appropriately expand the use of virtual health care post-pandemic. The following questions were raised for consideration by policymakers:

- Can states expand the use of compacts for virtual healthcare at large or at least in sectors like rural healthcare to improve access and lower barriers to care?
- Are changes needed to HIPAA to promote expanded access to virtual health care while protecting patient privacy?
- Can the government promote more Lego-like IT architectures with modular components in lieu of fully bespoke systems based on comprehensive, inflexible requirements that may inhibit adaptation for future use cases in a virtual health care platform?
- How can government policy, post-pandemic, promote virtual care to reduce the burden on healthcare providers? For example, automatically tagging key words to prepare prescriptions and then automatically ordering them could save time for providers and medical teams.

The pandemic had a transformational impact on healthcare delivery with the rapid adoption of and evolution of virtual healthcare technology. Key discussion points and focus areas for more rapid future adoption included:



Clinician Empowerment: It is critical to empower clinicians with more user-friendly tools rather than burdening them with additional technology.

Regulatory Challenges: At the onset of the pandemic, the regulatory landscape posed significant challenges, including difficulties with practicing across state lines and navigating reimbursement issues. Clearer advanced and exercised guidelines for emergency response events from government agencies could minimize some of these challenges. More importantly, we must consider how government policy can enhance virtual healthcare to ensure it is already robust before future emergencies occur.

Versatile Virtual Healthcare Toolsets: Versatile virtual healthcare toolsets to enhance remote patient monitoring, remote physical exams, digital stethoscopes, operational and payment functionalities, and a dispatch system for 9-1-1 calls can improve health outcomes in any emergency response. How are the FDA, through the medical device approval process, and other government agencies facilitating additional innovations in this space?

Innovative Solutions for Emergency Response: It was noted that an Uber-like medical staff dispatch system could facilitate more efficient matching of healthcare requests with available medical staff. ASPR could develop a national system to allow providers to sign up via a virtual healthcare platform in advance of an emergency to support local communities or first responders during an event. Such a system could serve as an immediate springboard in a future pandemic that, like COVID-19, does not impact all communities at the same time. Overall, the discussion highlighted the transformative impact of virtual healthcare technology, emphasizing the importance of user-centric design, regulatory clarity, and flexible, adaptable solutions to meet the evolving needs of healthcare delivery, both during the pandemic and in the inter-crisis period.

Build Automation into Electronic Health Records (EHR) Data Management Front End

Our healthcare system already involves significant computer usage, and automation could allow decision-makers to better leverage existing data and reduce the administrative burden on healthcare providers. The

healthcare enterprise typically uses Electronic Health Records (EHR) systems, which are focused on facilitating and tracking economic transactions rather than providing dynamic, real-time operational insights.

It was observed that EHR systems could be leveraged to automatically track usage rates of medical supplies. A panel member noted how our systems capture “I purchased this, I paid for it, I know what stock I should have” but not actual utilization taking place.

Hospitals and supply centers dealt with significant reporting burdens, especially during the pandemic, but the wide-scale usage of Electronic Hospital Records (EHRs) automatically generates a wealth of knowledge. It was suggested that de-identified patient data could be used to:

- Serve as a surveillance tracker for infectious diseases like seasonal flu to enhance supply distribution schedules for items like vaccines and identify non-standard infections for rapid identification of potential outbreaks.
 - It was noted several times that disease surveillance is an attractive use case for AI as it can summarize text and other data. An audience member from the field cautioned that accuracy often requires high volumes of data which may not exist for these use cases.
 - Leveraging statewide or federal health care system EHRs could serve as a jumping off point, assuming privacy and national security concerns are accommodated.
- The economic burden placed on hospitals, which operate on smaller margins than most realize, by manual reporting requirements was significant during the shutdown. It was not only the labor cost but the opportunity cost of shifting clinical staff (i.e., nurses) away from care points to reporting duties, like counting and submitting the number of available beds.
 - It was noted a hospital has a “finite set of employees trying to do everything at once, and now to incorporate reporting takes hours or days of FTE time out of daily operations like sourcing and restocking product.”
 - Further, we were reminded the standard of care

AI in Rare Events

The audience included expertise on the use of AI in medical operations. Audience members noted the challenges of using AI for predicting rare events like Ebola outbreaks.

- The scarcity of data presents a significant obstacle to AI's effectiveness in identifying rare occurrences, and synthetic data creation is constrained by the validity of its underlying assumptions.

- Large language models excel at understanding linguistic nuances and can extract salient features from clinical notes. However, converting unstructured text into standardized medical terminology remains challenging.

- AI was noted as having challenges aligning clinical care priorities with public health needs due to differences in context.

AI is one part of the ongoing effort to refine supply chain management. It has limitations, but especially when combined with statistical tools, it can enhance preparedness in the public and private sectors.

for patient delivery must be maintained, even as manual reporting burdens increase.

“AI is very good at finding cryptic correlations, relationships you didn't know existed. But it needs massive data to find outliers, because you're actually looking for something anomalous that deep learning models will tend to lose in the noise and misclassify routinely.”

- Audience Member Comment

The conversation underscored the complexities and challenges of not only operating a healthcare facility,

but also in distributing medical supplies and vaccines during the pandemic. The room broadly recognized the importance of equity, collaboration, and improved supply chain management in future preparedness efforts.

Overall, the panelists and audience highlighted the potential of AI to improve medical and emergency response operations while underscoring the need for appropriate integration. Collaboration with industry partners and leveraging experts in logistics management

was noted as an opportunity to enhance response capabilities during emergencies.

Government has a critical role in facilitating preparedness for rapid responses to health emergencies. The discussion on the pandemic highlighted challenges, things that worked well but could have worked better, and new opportunities to improve preparedness for future emergencies.

CONCLUSION

Summary of the Panel Discussions

The Common Healthcare Operating Panel

The event highlighted the importance of a Common Operating Picture (COP) to improve decision-making and resource allocation during a pandemic response.

The ESF-8 Council and HHS initiated a COP, under the name HHS Protect, during the COVID-19 response that facilitated the collection, integration, and sharing of COVID-19 data across federal agencies and with state, local, territorial, and tribal partners.

Observations from the private sector and academia documented the rapid development of the COP during the pandemic. It offers an example of how effective private-public collaboration can create a technology platform to support an emergency response. The discussion highlighted that:

- There is a need to sustain a COP framework and exercise it regularly to ensure immediate access to key data points in future emergencies, such as bed availability, medical supply levels, and patient counts;
- Additional advance planning is needed to establish common data languages, definitions, and agreements to avoid confusion and enable effective collaboration; and
- Flexibility and redundancy are essential to improve our preparedness and response posture for the future all-hazards health emergencies we are likely to face.

Data protection and privacy discussions must occur in

advance of an emergency. During a crisis, these elements underpin trust and transparency with the public. Uses of AI should be transparent and explained to the public in advance of the crisis to reduce criticism and unwarranted concern while providing decision-makers with more usable predictive data.

The panel highlighted the importance of leveraging existing resources, establishing robust standards, and fostering collaboration to address future health emergencies more effectively. Lessons from other agencies; military medicine; federal, state, and local responses; and public health were deemed valuable for enhancing the healthcare system's resilience.

In conclusion, innovative thinking, collaboration across sectors, and a proactive approach are needed to meet health emergency response challenges. The participants acknowledged the connections between healthcare and broader societal concerns, which extend beyond health policy to economic and national security considerations.

The Healthcare Delivery Panel

Participants acknowledged that the ESF-8 Council, HHS, and partner organizations understood the critical importance of the entire healthcare enterprise, including medical staff, hospitals, suppliers, manufactures, and logistics functions at all levels.

A positive lesson was that proactively leveraging and expanding private sector partnerships, especially to accelerate vaccine and therapeutic development, proved highly effective. Participants also agreed that the government continues to play a critical role in the

development of MCMs for health emergencies. To further accelerate the response to future health emergencies, the government should identify mechanisms to not only de-risk the MCM industry, but also foster collaboration through advance planning.

States and private industry adjusted healthcare delivery systems during the pandemic, including allowing cross-border medical practice and pausing non-critical procedures to increase staff capacity while reducing infection risk. The federal government's efforts to partner with industry collected more real-time data to better inform decision-makers facing challenging questions about how to allocate scarce resources.

Key challenges ranged from regulatory complexities to ensuring transparent, equitable distribution of limited resources across the nation. Looking forward, the review identified future opportunities for policymakers to focus on, including:

- Sustainable funding,
- Maintaining support once the crisis is in the rearview mirror, and
- Pre-crisis efforts to foster more international collaboration.

The discussion emphasized the importance of resilience, diversity, and security in medical supply chains, along with the need for enhanced virtual healthcare delivery and more specific efforts in healthcare delivery, including:

- Building automation into data management,
- Leveraging Electronic Health Records (EHR), and
- Exploring the potential of AI to improve surveillance and response capabilities.

Recommendations

The workshop identified the following four recommendations.

Finding 1. Common Operating Picture

Recommendation 1: *The U.S. government should establish and sustain a framework for a Common Operating Picture (COP) with clear criteria for activation during emergencies. The COP would create a system for storing*

relevant emergency response data and sharing it between government agencies.

The U.S. government role in an emergency response includes ensuring an ability to share and coordinate relevant information and resources, including in response to requests from states. To successfully carry out this role, the government should maintain, at a minimum, a common operating system of agreed-upon data definitions with a criteria-based set of rules for activating and de-activating the framework. The COVID-19 pandemic demonstrated that such a system provided significant value in support of the national response. This recommendation does not envision a continuously operating data system with private sector data elements, rather it envisions a framework that can rapidly be populated with real data and can be tested during exercises with either real or notional data to identify possible issues and train decision-makers in using it. It is not possible to perfectly identify what data elements will be required for a future response; however, we believe that by partnering with the private sector, the core elements can be defined (e.g., number of hospital beds, which will be relevant in any health emergency). The existence and routine exercising of such a structure will allow for data adjustments in a real event and more rapidly provide access to decision-relevant information.

Finding 2. Routine National, State, and Local Exercises

Recommendation 2: *The U.S. government should coordinate regular exercises of the national, state, and local responses to major health emergencies, such as pandemics, including tracking and implementing lessons learned.*

The 7th century poet and soldier Archilochus is attributed with the saying: “we don’t rise to the level of our expectations; we fall to the level of our training.” In the spirit of this centuries-old observation, the government should implement a coordinated exercise structure for routine all-of-government responses to major health emergencies, such as pandemics, on a routine battle rhythm. This should include phases for exercises at the state and certain local levels to pressure test assumptions and train decision-makers at all levels

of the response. Exercises should move beyond table-top or virtual exercises to include opportunities for in person role-play and interjections of unexpected events to build the mental resilience of policymakers. Every 24 months, the federal government should lead a capstone exercise that lasts at least 10 days and includes senior federal officials. Additionally, there should be a mechanism to track implementation of lessons learned, evaluated by the GAO with routine reports provided to Department Secretaries and Congress to facilitate implementation and support resource requests.

Finding 3. Second-Order Effects on Preparedness Posture

Recommendation 3: *U.S. government policymakers should carefully consider the second-order consequences of policies that have an impact on the healthcare industry, medical supply chains, or other sectors critical to the nation's health emergency preparedness.*

Like the waves created by throwing a rock into a lake, policies typically have significant ripple effects beyond their immediate targets. The U.S. government should actively encourage its workforce to exercise critical thinking skills and identify second and third-order effects of policy changes, especially for their impacts on the nation's preparedness for pandemics and other health emergencies. Not all unintended consequences are negative, but foreseeing these consequences is a major factor in ensuring the desired positive outcomes. For example, the U.S. government has made significant investments in expanding the nation's industrial base in the Personal Protection Equipment (PPE) industry. Congress and the Administration enacted the Make PPE in America Act, which requires several federal departments to source their PPE from the United States, although it also allows for waivers if domestically produced PPE is not available. However, in reviewing public waivers, it appears agencies seek broad waivers allowing companies to offshore the entire production process in lieu of limited waivers that would favor U.S. manufactures that offshore the production of only components not available from domestic suppliers. Medical exam gloves require the use of nitrile rubber or Nitrile Butadiene Rubber (NBR), which is not manufactured in the United States. Although

several federally supported or privately funded medical exam glove manufacturing facilities were established in the United States during or after the COVID-19 pandemic, the broad waivers currently sought under the Make PPE in America Act neglect these facilities in favor of cheaper foreign manufacturing because the U.S. manufacturers do not have access to domestic NBR. This results in unintended consequences by weakening the domestic medical supply chain and sending a signal to private investors that, despite its onshoring rhetoric, the government values procuring cheaper foreign medical supplies above supporting domestic manufacturers. This is just one example of how government policies should be pressure tested to identify unintended consequences and improve our nation's preparedness posture.

Finding 4. Coordinated, Layered Approach to Preparedness

Recommendation 4: *The U.S. government should pursue a layered and coordinated approach to improving preparedness involving extensive public-private partnership, government incentives, state-level collaboration, and improved supply chain management.*

The federal government serves a crucial role in incentivizing companies to develop medical countermeasures (MCMs) where there is no commercial market for such products. It must support and sustain a commercial pharmacy industry to ensure the capacity exists to develop and manufacture potential MCMs. State governments provide standards to support the medical certifications and licenses required to operate within their states. State and federal policymakers must look at how cross-state compacts can enhance normal medical care (e.g., for rural communities) and create a structure that allows for rapid expansion during emergencies. Just-in-time delivery of medical products reduces the cost of operations and supports a more efficient health care system during normal times. The U.S. government must explore how to leverage federal programs like Centers for Medicare & Medicaid Services (CMS) facility payments to incentivize hospitals to hold a supply bubble of critical PPE that may be needed for a local or state emergency response but not economically viable under the just-in-time supply model. This combined approach aims

to leverage existing commercial systems while building preparedness through public-private partnerships. The goal is to be more efficient and effective in future emergencies.

These recommendations are intended to challenge the reader to consider more ambitious solutions to prepare our nation for future pandemics and other health emergencies. Our team plans to conduct more workshops in this series, and we welcome suggested topic areas.



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— Lt. Gen. Brent Scowcroft, USAF (Ret.)

In Memoriam

Lieutenant General Brent Scowcroft

(March 19, 1925 - August 6, 2020)



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