WHITE PAPER

Evolution of Risk Mitigation in Value Analysis during the COVID-19 Pandemic

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AHVAP
Association of Healthcare Value Analysis Professionals

Introduction

The COVID-19 pandemic has exposed vulnerabilities on multiple levels in healthcare supply chains, particularly those associated with ensuring adequate supply of personal protective equipment (PPE) for healthcare providers, such as reported in *Frontline*[1] and *60 Minutes*[2] programs, and medications to treat patients.

Paradigm shifts during COVID-19 responses included healthcare service disruption (e.g., elective procedure shutdown), staff furloughs, and telehealth's voluminous growth. With reduced revenues still threatening, health systems combat intense pressure to ensure cost-effectiveness while struggling to address high demand for PPE; scarce, newly approved COVID-19 medications; and how to protect patients and staff. Technologies have emerged with promise to aid healthcare systems (e.g., in response to infection control) but have also lacked definitive safety and efficacy evidence.

While a devastating experience, the COVID-19 pandemic offers critical lessons. Supply chain and value analysis activities need greater integration, with clinicians deliberately engaged in processes. Alliances and collaborations must improve between industry and healthcare providers to help make a world-class health system in which all patients have equitable access to high-quality care. Finally, assessing clinical evidence on emerging technologies and therapies is critical to achieve positive patient and health system outcomes and prevent diversion of critical resources when supplies, finances, and staff are strained.

Recognize opportunities for improvement

The healthcare supply chain's primary function is to ensure the right supplies at the right time to deliver appropriate healthcare for each patient. To do this, healthcare organizations, manufacturers, suppliers, group purchasing organizations, and distributors must work together like a well-rehearsed orchestra. The COVID-19 pandemic acutely illustrated system challenges, such as disruption of medical supplies and unprecedented demand for PPE and certain pharmaceuticals.

PPE supply shortfall left healthcare organizations scrambling for supplies or engaging with nontraditional suppliers. Communities generously donated PPE to healthcare organizations, which required careful vetting and documentation to ensure clinical safety and efficacy for frontline staff, based on requirements established by clinicians in their system.

For example, at a Midwest healthcare system, any offer of isolation gowns necessitates a supplier-provided sample to review. Staff developed an assessment form to track each gown received and ensure it adhered to requirements identified by clinicians (i.e., approved, not approved). Often, the received gowns had no catalog number or supplier-tag identification, requiring the organization to create a system to catalog numbers and write one on each gown. Gowns also need review by different units of frontline staff to capture feedback.

Another COVID-19 effect on supply chain involved manufacturers discontinuing certain products to prioritize availability of other products associated with COVID-19 patient care. While prioritization is understandable during a pandemic, providers were often unaware of discontinuations because manufacturers did not timely inform them of changes. In some cases, providers learned of a product discontinuation only when placing a purchase order that was rejected because the item code or catalog number was no longer valid. Timely identification, vetting, and procurement of equivalent products can be difficult in these circumstances. Some scenarios included unique product types or sizes with no other option in the same category. Clinicians had to quickly pivot and develop different practices to meet patient needs. Such rapid changes also require staff education to avoid potential safety errors.

Disruptions with traditional suppliers continue to present some challenges. Products are allocated to existing customers only or available products are diverted to government stockpiles. Therefore, the need to use nontraditional suppliers continues. Nontraditional suppliers now (compared with pre-COVID-19) offer samples before sale, which affords the opportunity to vet the product's quality before purchase. Best practice is to test every sample product to ensure it meets industry and health system standards. Furthermore, ongoing testing should address variability within lots and subsequent deliveries.

Evaluate vulnerabilities to improve processes

COVID-19's disruption to longstanding relationships between providers and traditional suppliers necessitated providers pivoting to nontraditional suppliers. Existing relationships helped some providers source products from nontraditional suppliers; however, others faced navigating hundreds of suppliers for a single product category with only a handful of viable options. Providers learned quickly that nontraditional suppliers, especially international suppliers, needed thorough, rapid, and *repeated* vetting. Many suppliers entering the marketplace failed to deliver quality products that would protect patients and staff. Health systems lacked tools to accomplish careful vetting.

The U.S. Department of Health and Human Services' Office of Inspector General Exclusions Database[3] lists individuals or entities with exclusions or sanctions prohibiting conduct of business in the United States. As an example of a cooperative effort, ECRI and the Association for Health Care Resource & Materials Management (AHRMM) collaborate to offer providers assurance about nontraditional suppliers offering PPE supplies; AHRMM tracks nontraditional domestic suppliers,[4] and ECRI tracks nontraditional international suppliers.[5]

When considering nontraditional suppliers, basic prequalifying questions include who, what, when, and where. Once a supplier clears prequalification, vetting procedures specific to the provider's healthcare system can proceed. Providers can also request product samples if they receive the necessary vetting information. The following list is derived from AHRMM, Association of Healthcare Value Analysis Professionals (AHVAP), and ECRI input:

- Name and contact information of supplier and referral(s) (e.g., whether entity currently supplies healthcare industry, three U.S. systems supplied by entity, brands and manufacturers represented by entity)
- Availability of product samples
- Location details (e.g., products currently physically in or offered in United States, whether supplies can be delivered for review, country of origin, origin of raw materials)
- Website verification
- Safety and quality issues
- Product specifications
- Accreditations and compliance with industry standards
- FDA registration
- Product photographs
- Tax ID (domestic)
- Buying options
- Delivery terms
- Sample for evaluation

Additional criteria specific to provider processes can include provider confirmation about product legitimacy (e.g., reference check) and confirmation from the manufacturer.

While the pandemic exposed supply chain vulnerabilities, it also revealed opportunities for future risk mitigation, such as the following:

- **Track and monitor country of origin for as many products as possible.** Several years ago, providers were unaware of the volume of intravenous solutions manufactured in Puerto Rico until it was too late. COVID-19 revealed reliance on products manufactured in Asia. Monitoring triggers (e.g., weather, political disruption) in country of origin may offer time to pivot to backup plans.
- **Reevaluate inventory models.** Providers using just-in-time inventory models experienced the earliest effects of PPE supply chain disruption. Now, providers are expanding warehouses and stock levels to align with government mandates and beyond.
- **Reevaluate partnerships and collaborations with suppliers, distributors, and group purchasing organizations.** Some of these entities met challenges during the pandemic, and others did not (e.g., communication disruptions amid out-of-stock situations, unreliable timelines on product availability, ineffective communication to member organizations).

Examine clinical evidence about technology

Looking through the disruption lens

Disruption is defined as a radical change in an industry or business strategy, especially involving the introduction of a new product or service that creates a new market. Emerging technology can streamline care in ways not experienced before in a global sense or create a new path to an individual provider or manufacturer stakeholder. Since 2015, AHVAP has embraced this view of new technology in its educational programs, from the collaborative development of the value analysis maturity curve to member presentations and peer-reviewed articles.

The disruptive technology frontier pushes the United States closer to its goal of value-based care, which pays providers based on patient health outcomes. By measuring health outcomes against the cost of delivering those outcomes, the overall value of care may be improved. An evidence-based approach is a core tenet of value analysis, in which Value is equal to the Quality of the Outcomes divided by Costs to provide them, or V = Q/C. The measure of disruptive technology in the face of little to no evidence must be carefully considered. The question to ask every time is "will it be worth the risk to use the new technology for an agreed-upon time frame based on mutual goal(s) in which the intended technology is expected to improve care?"

> In November 2019, AHVAP and AHRMM members attended an invitation-only Value-based Care Summit with 40 thought leaders to discuss these and other assumptions of how U.S. healthcare can turn its collective learnings into value.

Understanding the importance of evidence during the pandemic

A pandemic heightens interest in new technologies and new strategies that may lack conclusive evidence by virtue of being new, which is the case with many of FDA's Emergency Use Authorizations. Pursuing the latest trend or technology to supplement established strategies can be an expensive mistake or fall short of the intended benefit.

For example, assessment of the clinical evidence on infrared temperature screening programs to reduce infection transmission by visitors and staff at health facilities during infection outbreaks found that these programs generally fail to identify most infected persons; more than half of those screened through such programs go undetected.[6] Further, with COVID-19, about half of infectious individuals are asymptomatic. A health system's staff and patients may be better served if leadership expends resources on measures known to work (e.g., social distancing, wearing masks, controlling entry to facilities to separate those working in COVID-19 wards from those working in other patient care areas). When reporting on healthcare systems that had deployed such programs a few months into the pandemic, *Wired Magazine* stated one California organization spent about $20,000 on infrared screening technology.[7]

> The systematic process of health care horizon scanning identifies technologies with the potential to cause future disruptions (positive or negative). One example is the PCORI Health Care Horizon Scanning System (HCHSS), maintained under contract by ECRI, which identifies and monitors technologies that might be available for clinical use within three years. An HCHSS COVID-19 supplement monitors and reports on emerging topics with high-impact potential for patient outcomes within 12 months (e.g., diagnostics, preventive measures, system changes).

When considering how well *any* technology works, the PICOTS framework is used to develop key questions. The framework refers to the **P**atient population in whom technology will be used, the **I**ntervention or technology being used, **C**omparator technologies, **O**utcomes to be measured, **T**ime frame for measuring the outcomes, and care *S*etting in which the technology will be used. Clinical evidence is then sought to address the key questions.

Leveraging change to improve engagement

During a November 2020 virtual seminar, value analysis and supply chain healthcare professionals responded to a poll about how COVID-19 pressures changed value analysis processes at their hospitals or health systems, indicating they have experienced more C-suite engagement (29%) than less (4%) and more physician engagement (23%) than less (20%).[8]

Discussing the results, Andrew Furman, MD, MMM, executive director of ECRI's Clinical Excellence team and an emergency physician, reflected on changes wrought by the pandemic. For example, he never thought he would need to address questions about splitting ventilators for multiple patients[9] or extended reuse of N95 respirators[10] as he had to early in the pandemic when providers were searching for information and options in response to supply shortages. Greater C-suite engagement is encouraging as leadership remains invested in how to keep staff safe while caring for patients. Similar percentages of more and less physician engagement may reflect changing care processes, such as cessation and resumption of elective procedures and conversion to telehealth visits.

Recall, too, that you can *capitalize* on the change, according to Furman. "Since everything has changed, it gives you the chance and the opportunity to also step back and say 'what does our value analysis process look like, and what should it be?'" he said.

While value analysis professionals might encounter physicians who are overworked supporting patients and changes resulting from the pandemic, the poll results suggest many physicians want to be part of the change process to achieve better evidence-based care. Even the dialogue associated with obtaining clinical acceptance of PPE items is an opportunity. "If you hit a wall [before], that wall might be gone now, because everybody's mindset is a little different," Furman said.

Conclusion

The COVID-19 pandemic has disrupted and transformed healthcare supply chain and value analysis. AHVAP and ECRI recommend adding vetting of nontraditional suppliers to standard practice in value analysis. As value analysis teams continue activity and adapt to changes wrought by COVID-19, examining clinical evidence on emerging technologies and using this evidence to engage clinicians remain critical to avoiding poor investments and negative outcomes.

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Joint Statement

ECRI and the Association of Healthcare Value Analysis Professionals (AHVAP) have collaborated to bring members and value analysis professionals this content. We acknowledge the many contributors who have made this project possible and give a special thank you to all the healthcare workers who have dedicated their lives to helping others, including tireless efforts at the front lines during the COVID-19 pandemic.

About ECRI

ECRI is an independent, nonprofit organization improving the safety, quality, and cost-effectiveness of care across all healthcare settings. With a focus on patient safety, evidence-based medicine, and health technology decision solutions, ECRI is the trusted expert for healthcare leaders and agencies worldwide. For additional resources, see ECRI's COVID-19 Resource Center and PPE testing services. The Institute for Safe Medication Practices (ISMP) is an ECRI affiliate. Visit ecri.org and follow @ECRI_Org.

About AHVAP

The Association of Healthcare Value Analysis Professionals (AHVAP) is an organization of professionals whose expertise bridges the gap between clinical and supply chain process. Through the use of evidence, clinical and financial expertise value analysis facilitators play a pivotal role to ensure effective decision making that positively impacts clinical, operational, and financial outcomes. For more information, visit AHVAP.org, LinkedIn, or follow @AHVAP on Twitter or Facebook.