COVID-19: Shaping the Next Normal in the Pharma Ecosystem

Part 2: Engaging and collaborating with multiple stakeholders to redefine value through COVID-19 lessons

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The COVID-19 pandemic has pressure-tested the U.S. healthcare system, exposing shortcomings that we can no longer ignore or hope will go away. COVID-19 has laid bare the system's financial, resource, and coordination challenges and its struggles to provide value to all.

Consider what we have seen since mid-March — the point at which all 50 states, the District of Columbia, and four U.S. territories had reported at least one case of COVID-19:[1]

- The healthcare delivery system found itself unprepared, owing in part to a misalignment of resources and priorities[2,3]
- Payers, ambushed by the speed of COVID-19's spread, are bracing today for a huge bill for coronavirus care — and an even bigger one tomorrow as pent-up demand spikes[4,5]
- Many patients have been sidelined, inundated with information about COVID-19 prevention yet unable to either access or afford needed non-COVID-19–related care

To prevent a recurrence of symptoms like these after this crisis fades, we will need to reinvent the system. Doing so will take several strategies built around a single focus: returning the patient to the center of care. Because patients understand their journey in a way no one else does, interventions must show value to multiple stakeholders, including the patient and/or families and caregivers.

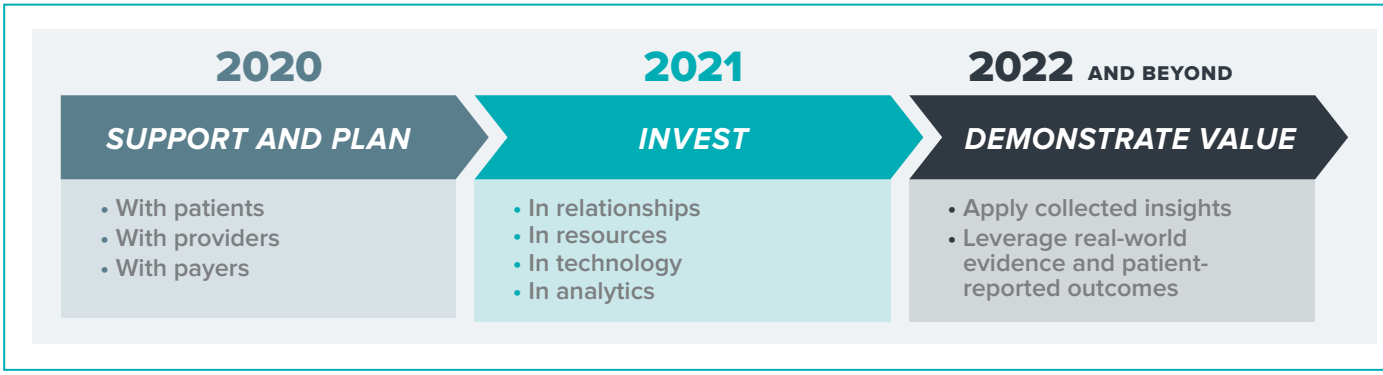
What's best for the patient should drive stakeholders' efforts to collaborate on priorities. The combined biotechnology and pharmaceutical industry has an opportunity to lead that process. In this article, we describe the steps, cooperation, and capabilities manufacturers will need to work with others to achieve a patient-focused, evidence-based system built around shared value.

THIS YEAR: *SUPPORT AND PLAN*

Ultimately, the scourge of COVID-19 will end through the discovery of vaccines and treatments and the cultivation of herd immunity. But the immediate concern has been in containing the spread of the virus. Similarly, at this stage, biopharma companies' public focus should be not only on their pipelines, but on how they can help future collaborators — patients, clinicians, and payers — tend to basic needs now. It's also a good time to lay the groundwork for the tasks that lie ahead for manufacturers.

With patients

As the twin public health and economic emergencies play out, for people with chronic conditions the immediate need is to stay on their medications. To that end, biopharma can ramp up patient education and adherence support programs. Expanding patient assistance program (PAP) guidelines to the extent allowable can help with affordability. Most of those who have lost their commercial coverage won't be eligible for traditional coupon programs.



Beyond your own walls, work with payers and legislators to enact temporary waivers on PAP eligibility limits. Nearly all states are struggling with Medicaid budgets, and many enrollees are having trouble accessing services.[6] A compelling case can be made that easing restrictions on PAP enrollment may help states to contain costs by helping patients adhere to their treatment regimens — and thus avoid exacerbation of chronic conditions.

This is also a good time to build bonds with patients. Ensure that hubs, specialty pharmacies, and others are reaching out to high-risk patients. Is a case manager following up with a patient with multiple sclerosis to check mobility? Or with a patient who has rheumatoid arthritis to ask about joint pain? With a patient with schizophrenia whose refill claims have fallen off?

Some high-touch activities may be most efficiently conducted through interactive virtual models. Work with your hub to develop engaging tools that ease barriers to care and help patients track their care journey. An introductory step may be the collection of patient-reported outcomes (PROs) by a pharmacist or care manager as part of the patient engagement process. With patient consent, this process allows you to collect PROs that will help to support value creation down the road.

With providers

With sales representatives unable to get into provider offices, it's a good time to consider the degree to which provider-focused activities are effective or efficient.

Start with virtual meetings. Knowing that physicians were less engaged in video meetings than in-person calls, drug makers tried them only on a limited basis before COVID-19; Veeva Systems estimates that sales representatives used its software to facilitate fewer than 5,000 online meetings with physicians in January. In April, the number of online meetings ballooned to 317,000.[7] Now that you have their attention, how can you make virtual meetings more effective and interactive?

Even with furloughs slowly being lifted, a physician's access to his or her own office staff will be limited as long as social distancing remains in effect. Office staff are a critical link in the access chain between patients and their medications, working out coverage of a drug the physician writes for a patient. "How do I initiate a benefit investigation?" is but one example of what a physician may need to know to keep a patient who is stable on a drug. Venues such as Skipta or Sermo can provide peer support for instances like this and other opportunities for self-learning.

On the research and development side, begin talking with research clinicians to rethink the future of clinical trial design and what they choose to present to the FDA. Studies based on **non-inferiority** — an unfortunate choice of terminology — don't communicate a common vision of value. Biopharma must demonstrate how a drug can help patients as they move through the continuum of care, and at the same time benefit all stakeholders in a meaningful way through outcome and/or cost improvements.

With payers and risk-bearing provider organizations

With large trade gatherings such as AMCP 2020 being cancelled and with P&T committees either inaccessible or meeting with stripped-down agendas, consider alternatives for reaching out to payers. As large phase 3 trials of new drugs remain on hold, talk with payers about how they define value for the product or the disease state and what evidence of value they need to see for drugs that are approved at earlier phases of the development process. Engaging with payers on real-world evidence (RWE) remains rooted in claims data, but seek to develop pathways to work with payers to collect clinical data from EMRs and other sources. The goal is to combine claims data with clinical and patient data to show benefit to all potential stakeholders.

The delay of many elective services from this year to next — on top of the expense of caring for members with COVID-19 — has payers fearing a reckoning like none other. Cost pressures may push them toward the use of global capitation. Probe payers about their attitude toward global budgets, what that might look like, and how it may affect your portfolio.

Some sleuthing about the future of cost sharing may be wise as well. Healthcare is elastic, and the economic disruption will affect some patients' ability — or willingness — to pay for services and products. What benefit packages will emerge from insurers and employers? How will Medicaid payers adapt to the cost pressures they face, especially if the Center for Medicare & Medicaid Services' proposed "Healthy Adult Opportunity" federal funding formula is enacted? Critics warn that strained Medicaid budgets make up an example of how financing Medicaid through fixed block grants would leave the program underfunded during a public health crisis.[8]

NEXT YEAR: *INVEST*

If 2020 is a time to "get the lay of the land," 2021 will be the time to make investments in relationships, resources, technology, and analytics, to move toward the collaborative ecosystem of the future.

Relationships and resources

With guideline development generally put on hold during the COVID-19 crisis, insights beyond those to be gleaned from claims are needed. PROs — a subset of RWE — can be timely tools for payers and prescribers looking for a starting point for appropriate management of new drug products, especially those where the primary benefits are improvement in patient symptoms or slowing disease progression, where claims and clinical data are less likely to be revealing.

One strategy for crafting those insights is to create a common-interest coalition, working with patient advocacy groups or organizations like the National Organization for Rare Disorders to understand what patients value. Through this kind of collaborative approach, coalitions can develop a patient-focused vision for standards of care in the use of products receiving early FDA approval. In the absence of guidelines, payers and prescribers will need help understanding these new therapies and may be open to alternatives to phase 3 data.

The output, combined with clinical and cost data, might be similar to the National Comprehensive Cancer Network's (NCCN) "evidence blocks," the Institute for Clinical and Economic Review (ICER) Value Assessment Framework, or the American Society of Clinical Oncology's (ASCO) Value Framework, which are intended to drive conversations between clinicians and patients.[9] Another potential resource may be care maps that help prescribers to understand a product's place in therapy.

Whatever form a consensus document takes, work with stakeholders to develop ways to disseminate it. For instance, if partnering with health systems to improve navigator services or providing tips for making telehealth meetings more meaningful, include prompts that encourage patients to ask clinicians about standards of care for new products.

Work with prescribers and payers to learn what resources they would find useful. The "next normal" may embrace shared knowledge and trusted authority as a way of reducing unwarranted variation of care.[10]

Technology

After Congress loosened reimbursement restrictions for telehealth, many experts predicted that as long as the modality can get beyond state regulatory hurdles, it will have staying power.[11] The more

Using RWE to inform contracting

Value-based contracting (VBC) generally prices a drug on the basis of benefits that have been measured previously, such as clinical trials. **Outcomes-based contracting** (OBC) is a value-based contract design that ties drug reimbursement to actual health outcomes. RWE can drive which products are suited for outcomes-based contracting, while OBC itself is a tool for collecting RWE from multiple stakeholders.

Consider these questions:

- ***What kinds of outcomes can be collected and measured in various patient populations?***
- ***Which of those outcomes can you show within the time frame of the contract to show overall value?***
- ***Are you providing, collecting, and sharing data that can support use of your product?***

"Data obtained from outcomes-based contracts can help to assure that the right patient is getting the right treatment at the right time, resulting in the best possible result," says Vargo. "In addition, outcomes data will give payers a real-world validation of the value unique treatments bring to the healthcare system."

patients become comfortable with it and want to use it, the more providers will adapt.

The new communications platforms can be used to share data and insights remotely with key specialists or with physicians in remote areas not traditionally assigned a sales representative. Similarly, video calls could be a way for a medical services liaison or a key opinion leader (KOL) to answer rural physicians' questions about new products. For some specialists in remote locations, it may not be possible to consult with another specialist in their county or region.

"Technology will allow life science companies to more easily demonstrate the value of their products through capture of not only real-world evidence but also real-time evidence," says Jim Clement, a partner at Coeus Consulting Group.

For KOLs on biopharmaceutical companies' speaker bureaus, virtual engagements may become more commonplace. Consider what technological resources may be needed to enable prescribers on the receiving end of these meetings to participate.

Analytics

For all the time and money invested in relationships, resources, hardware, and software, it's critical to know whether these new approaches are working.

Data analytics can provide the answers. Organizations that invest in data systems and analytics can begin to combine the PRO data that hubs have started to collect with data from traditional sources, measure the appropriateness and effectiveness of the new communication channels with patients and providers, and yield insights that provide opportunities to partner with payers on outreach or support programs. Payers are demanding more RWE data from manufacturers while starting to cultivate their own programs.[12] It will be key to meet these needs, to help payers integrate more RWE into their decision-making and patient care programs.

Data-driven decision-making will be essential to coping with the effects of the COVID-19 crisis and to becoming resilient after it has passed. Insight-driven organizations will prosper because they ask good questions and gather relevant information.[13]

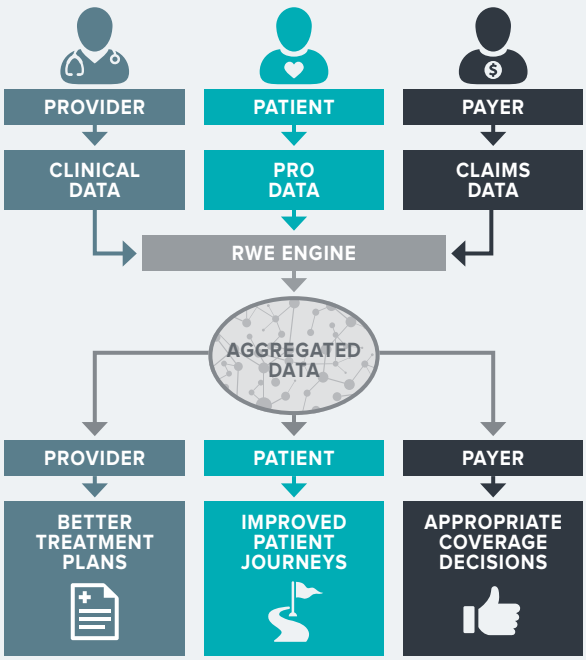
TWO YEARS FROM NOW: *DEMONSTRATE VALUE*

For plan years 2020 and 2021, many payers will have been making decisions while flying without robust data. Now, as payers settle into more "normal" routines, the efforts and investments biopharma has made over the last two years will pay dividends for all. At this stage, manufacturers have robust data to share from multiple perspectives — patient, payer, and provider — and a golden opportunity to prove value.

Take those PROs that biopharma will have collected for two years. Mined for insights and shared with providers, PROs now form the basis of new and thoughtful conversations between patients and clinicians about a healthcare intervention.

Flow of real-world evidence

Real-world experience reported by patients, providers, and payers feeds a robust pool of RWE that can be used to improve prescribing decisions and plan design. Arrows depict the flow of information. In this model, the patient's voice — a critical component of value — is heard.



The RWE generated in a model like this can be used to support provider participation in alternative payment models. It also can be built into product value propositions for payers and used to tailor offerings for specific patient populations and subpopulations.

Payers can layer PROs into their own predictive analytics and patient stratification tools to help providers with clinical and risk assessments.

Out of the box? That's the point. "Life science companies are going to have to find unique ways to be relevant to payers," says Harry J. Vargo, RPh, a partner at Coeus Consulting Group.

With the advent of risk contracts, payers and providers have become much more cooperative about sharing their clinical and claims experience with one another. Adding PROs to the mix helps manufacturers to round out a robust set of RWE that supports all parties — especially patients.

RECOMMENDATIONS AND CONCLUSIONS

Clearly, this series of steps is ambitious. It will require investment and dedicated resources. But it's disruptive and creates positive systemic change. It's a roadmap for leadership in a healthcare system in need of visionaries driven to help it emerge stronger from this crisis.

Lasting change will occur if it is done with an eye toward collective benefit. Collaboration is essential. Manufacturers that share data with prescribers and payers help to fulfill their post-marketing obligations to track patients' outcomes over time. The RWE generated as a result of mutual data sharing provides a benefit to all present and future patients.

The key is for manufacturers to be proactive. Begin with small, fundamental steps now, in the "support-and-plan" phase:

- Thoroughly evaluate the short- and long-term needs of customers, including patients, payers, and prescribers
- Establish a reengagement team in each market. This group would be responsible for running analytics to inform when to reengage the market
- Launch a scenario-based strategic planning effort to prepare for different outcomes in different locations (e.g., are things "returning to normal" in one area but not another?)
- Mobilize strategic working groups to scale up and accelerate initiatives

Once reengaged, consider the steps described in the "invest" and "execute" phases. Ultimately working toward the generation of RWE, manufacturers should share what they know about their products. This helps to support providers — who see what's happening in a patient — in their efforts to provide the very best care. And it supports payers, whose own data track the overall cost of care. RWE reveals a drug's true benefit, incorporating data that providers and payers on their own wouldn't be able to generate.

The result of this process helps to promote conversations about real value. And that is the essence of patient-focused care.

Companies willing to rethink how to meet customer needs and expectations in timely and collaborative ways will be best positioned to adapt to the "next normal." To come out of the crisis stronger, all should work together to ensure that the future will look different from the past.

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