

DESIGN LAB BRIEFING

Transforming the Real-World Evidence Environment to Accelerate Value-Based Payment Innovation for Biomedical Products

September 2023

Background

Value-based contracts tracking patient outcomes have been operational in the United States for nearly two decades. Despite the engagement of numerous payer organizations in at least one arrangement, challenges persist in scaling and implementation. Stakeholders most commonly report contract negotiations stall due to limited data availability, inaccessibility of meaningful outcomes, and high implementation costs¹. Available staff resources, misaligned time horizons, and implementation obstacles impede the system from realizing the benefits of value-based contracting.

The growing availability and investment in scalable real-world data (RWD) infrastructures offer improved capabilities to track and learn from patient outcomes over time. Yet, these systems fall short of the needs of payers and other stakeholders². Data linkages and efficient analyses are not easily accomplished without significant investments in time and resources. In addition, evolving security and privacy requirements add concerns, costs, and complexities.

While technology-enabled solutions are emerging to aid evidence generation and value-based contract implementation, they can also contribute to interoperability concerns. Rather than creating more systematic or practical approaches, these solutions can exacerbate data fragmentation and confusion among stakeholders.

Waiting for technology and RWD to mature comes at a significant cost. Gaps in evidence result in clinical waste due to overtreatment, low-value care, or care not aligned with patient goals. Additionally, administrative complexities and pricing failures contribute to further operating system costs. These inefficiencies collectively contribute nearly \$680B in healthcare waste annually in the US³.

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Beyond the economic consequences, incomplete and inefficient evidence creates confusion among stakeholders, prioritizes treatments based on cost over value, and stalls biomedical innovation. Simply put, the sustainability of the healthcare system can't afford to overlook the evidence gaps and operational inefficiencies.

There is a need to accelerate outcomes tracking to enable payment innovation. Leveraging existing RWD and real-world evidence (RWE) platforms can facilitate the scalable implementation of value-based contracts. Over time, these enhanced capabilities promise to minimize clinical, operational, and administrative waste while fostering a more sustainable healthcare system.

Our objective in NEWDIGS is to catalyze this evolution of the current RWE environment into a more efficient “marketplace” that fuels improvements by paying for value and patient outcomes while also meeting the needs of all stakeholders in the system.

Approach

This concept overview builds on discussions at the NEWDIGS LEAPS Design Lab in June 2023, including a provocative comment by one panelist:

“I think we [solution providers] are becoming part of the problem,” referring to the fragmentation of RWD and RWE exacerbated by single-purpose solutions to address value-based contracting implementation challenges.

He further commented, *“We all need to be part of a common infrastructure.”* This seemed like a good place to begin our exploration — What are the specific gaps we need to address? What kind of a new RWE environment could help to address them?

We conducted a literature scan to identify the common challenges, critical features, and change drivers. In July and August, we further explored these issues with targeted interviews with ten leaders from payer, solution provider, patient advocacy, research, and life science communities.

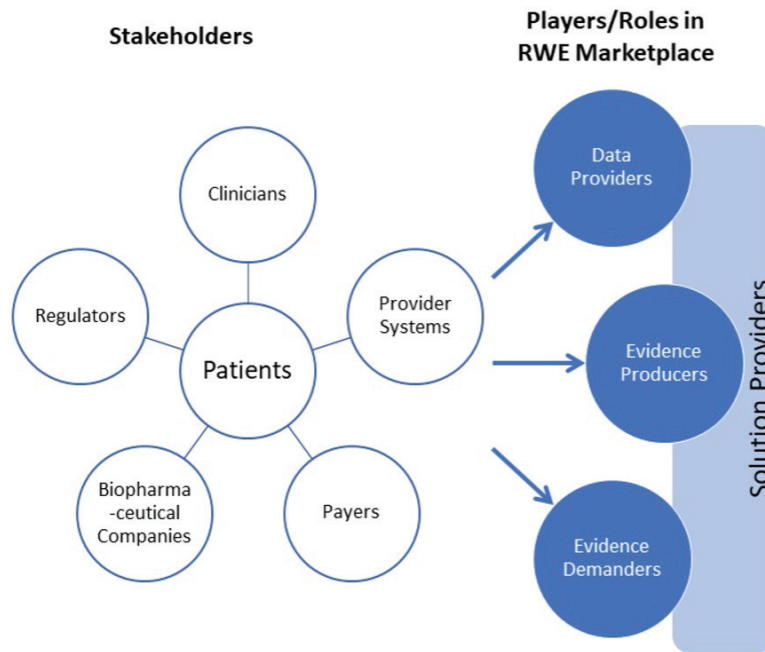
New Marketplace

While interviewing the stakeholders, we quickly realized that the perspectives represented fell into three categories. While any stakeholder could play more than one of these roles, each had different needs. These included:

1. Data Providers — owners of the RWD needed to produce RWE.
2. Evidence Producers — those who analyze the RWD to produce RWE.
3. Evidence Demanders — key decision makers who need RWE to make decisions for value-based contracts and payment innovation.

In addition, solution providers can serve as enablers connecting the various roles in the RWE market for outcomes-tracking and value-based contracts. Often not considered traditional healthcare stakeholders, these organizations offer some combination of data, evidence, and/or decision-support products or services to support value-based payment innovations. (See Figure 1)

Figure 1. Stakeholders and Roles for Outcomes Tracking Capabilities*



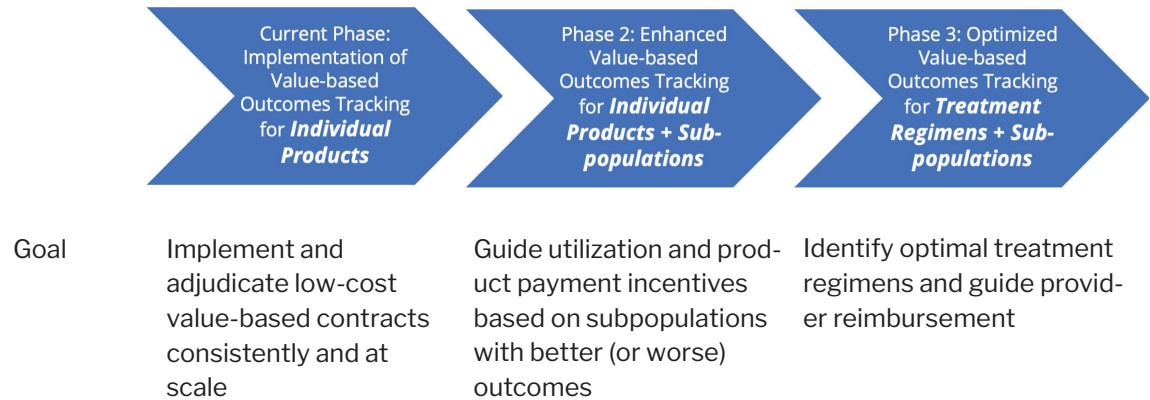
**Traditionally defined stakeholders in the healthcare system can play any or all roles in outcomes-based tracking for value-based contracts.*

Current Status and Need for Enhanced RWE Environment to Accelerate Payment Innovation

Value-based contracts demand the allocation of different staff, time, and resources than market-share-based rebate contracts. Reducing the investments required for outcomes tracking and adjudication through efficient, low-cost, and timely real-world data access is critical now. As value-based contracts have proliferated, ongoing efforts concentrate on applying simple and clear outcome metrics accessible in existing payer data (e.g., claims) and developing processes and infrastructure to enable implementation at scale.

Yet, the potential for value-based contracts to significantly reduce clinical, operational, and administrative inefficiencies will not be achieved without enhanced capabilities over time. For example, reducing clinical waste – i.e., getting the right treatment to the right patient faster – will require learning from outcomes tracking and shifting from a one-size-fits-all approach to incentivizing payment for targeted therapies based on subpopulations and treatment regimens. (See Figure 2)

Figure 2. Value-Based Outcomes Tracking for Drug Therapies to Reduce Health Care Waste



These phases will require a staged evolution of capabilities (e.g., outcomes, patient and payer populations, data expectations, reporting characteristics, and emerging capabilities). Over time, the system will be able to move from implementation at scale to more aligned utilization and optimized payment.

When asked, “What are you unable to do now that you hope this new environment could enable?” interviewees highlighted several vital functions:

- Enable low-cost, quick adjudication of fit-for-purpose outcomes tracking using existing RWD infrastructures at scale.
- Increase awareness of what technologies and organizational capabilities exist.
- Find potential partners, collaborators, and solution providers “that I need” more efficiently.
- Identify opportunities for interoperability and scalability among solution providers.
- Learn more about what others are doing to accelerate best practices in emerging value-based payment models and benchmark their organizational performance. (Of note: there is more interest in learning from others than sharing with others.)

Additionally, the new environment would need to enable pre-competitive collaboration while respecting the commercial interests of the stakeholders — balancing the boundaries between collaboration and competition.

Capability Gaps

Interviewees identified several capability gaps related to processes, policies, technologies, incentives, and human capital. The following should be viewed as illustrative needs rather than a comprehensive inventory of gaps.

Processes

Compared to payment based on market-share rebates, value-based contracts require changes from current practice and may be more complex to administer and financially uncertain. Organizations with multiple contract experiences have created efficiencies and reduced implementation time and costs. Scaling contracts requires processes that further reduce operational efforts. Process gaps include:

- Lack of accessible outcome measures identified by and aligned with evidence demanders early in the product development lifecycle to allow adequate market preparation and measurement.
- Complex evidence production, which requires value-based contract capabilities to build iteratively.
- Limited ability among data providers and evidence producers to enrich available data with novel targeted data collection (e.g., prior authorization, specialty pharmacy partnerships, provider registries).
- Absence of standards and generalizable practices for preparing, executing, and documenting operational procedures.

“Is it more resource intensive than a market-share rebate? Yes, but once you start getting these going, aspects are repeatable.” — Health plan

“The process for developing value-based contracts breaks down if there is not a willingness to commit to the outcomes early enough in the product development for the outcomes to be well-established in the system.” — Patient advocacy organization

A collective understanding of processes and practices would allow collaboration between data providers, evidence producers, evidence demanders, and solution providers to optimize outcomes-tracking capabilities and reduce operational costs.

Policies

Tracking outcomes requires protected health information. Policies that define appropriate data use controls, address privacy and security requirements, enable anonymized data or evidence exchange, protect intellectual property, and support transparency are needed. Examples of policy challenges include:

- Unclear data access policies for data queries and access controls.
- Unclear and variable privacy and security standards and expectations across organizations.
- Lack of enhanced security protocols to enable outcomes tracking among small populations.
- Limited collaboration and learning among state Medicaid organizations impeding collective advancement of knowledge and efficient operationalization among resource-constrained organizations.

“A systems approach is needed. Otherwise, we’re Sisyphus pushing the boulder up the hill. We need foundational things, requirements for security, privacy considerations to start the discussion.” — VBC subject matter expert

“The infrastructure will need a core and stable central structure or spine with modular components to help with flexibility and agility. That flexibility will allow us to move faster across different needs and be locally relevant.” — Biopharmaceutical company

Reducing the ambiguities of privacy and security requirements and providing guidance on appropriate technology use is needed. Policies that enable — rather than hinder — operational efficiencies can provide stability for value-based contract implementation.

Technology

Emerging and evolving technologies hold the promise for improved scalability. Technologies can enable broader outcomes tracking, reduce data fragmentation, anonymize data, ensure robust encryption, control access, and provide greater operational efficiency. In addition, the ability to connect disparate data from patient sensors or wearables, clinical data, or social determinants of health information to facilitate more meaningful outcomes is desired. Data tokenization to address patient mobility as members move in and out of health plans or employment, allowing improved tracking over time, remains nascent. Artificial intelligence or machine learning solutions to automate the collection, adjudication, and reporting are still maturing. Blockchain can streamline the reconciliation process between developers and payers for invoicing and create secure linkages involving siloed data sets and separate administrative systems but remains underdeveloped⁴. Examples of technology-related gaps include:

- Inconsistent awareness and ability to classify emerging technology.
- Lack of interoperability to enable scale across technology, systems, and platforms.
- Absence of clear market signals to identify technology gaps and spur innovation and adoption.

“It’s very confusing for payers to understand all the emerging technologies. They don’t have time to figure this out; they just want to work with somebody to execute innovative contracts in the real world. We are almost creating more confusion in the market rather than creating a clear path” — Solution provider

Shared insights regarding emerging technologies can help data providers, evidence producers, and evidence demanders identify the most suitable solutions, develop in-house capabilities, or partner with solution providers. Without a global and holistic view, the technologies meant to aid the scale and implementation will further exacerbate fragmentation and waste.

Incentives

Value-based contracts require commitments beyond the standard market-share rebates. Incentives — including bonuses, penalties, or mandates — can spur evidence generation, support needed infrastructure, and encourage stakeholder participation. Examples of incentive challenges include:

- Misalignment of incentives for data providers to improve and enhance data collection or provide access to evidence producers and evidence demanders.
- Inadequate investments in data and operational infrastructure.
- Constrained outcomes tracking capabilities in public payer programs (e.g., state Medicaid) due to regulations and budgetary resources or private sector data security and use policies.
- Limited incentives for evidence demanders to adopt value-based care as an alternative to other health system sustainability solutions (e.g., price caps, restrictive coverage policies, etc.)

“In our commercial line of business, we meet with clients who are upset about increased costs. We are able to say these are the things we are doing. We’re looking to make sure that this drug is performing the way it should. We’re actually looking at outcomes.” — Health plan

*“Nothing has happened to accelerate data standards in this county that hasn’t been mandated. When it got mandated, suddenly everybody figures out the way to do it.”
— VBC subject matter expert*

Carefully designed incentives can promote stakeholder engagement, while regulations and penalties can ensure compliance. Striking a balance between incentives, consequences, and mandates is critical to avoid unintended consequences.

Human Capital

People and leadership across all levels of all stakeholders are foundational to optimizing outcomes-tracking capabilities. This includes individuals directly engaging in value-based contracts, executive leadership within organizations, and cross-stakeholder capabilities. Gaps identified included:

- Limited in-house capabilities or existing business partnerships to implement value-based contracts.
- Need to extend and augment talent directly and indirectly engaged in outcomes tracking and facilitate change management within the organization.
- Leadership commitment to value-based care reinforced by aligned organizational priorities and investments.
- Lack of a trusted voice to facilitate cross-organizational exchange and education.

“A common infrastructure is the only way that can work. If we all set out to our own thing, it’s never going to be a cohesive approach. If it’s not driven from the top, it’s all of us trying to solve our individual needs. Not solving for the global need.” — Health plan

Efforts beyond technology and infrastructure will be needed to drive the scale of value-based contracts. Multistakeholder forums, executive sponsorship within individual organizations, and talent development are necessary to reduce the gaps in evidence and waste due to operational inefficiencies and support payment innovation for biomedical products.

Where Do We Go from Here

Over the coming months, we will conduct stakeholder mapping and additional interviews to sharpen our vision for a new RWE environment that addresses the challenges and leverages the opportunities emerging in our discussions. We look forward to a deep dive into the evolving RWE environment for value-based outcomes tracking concept at our Design Lab in April 2024.

How you can get involved:

1. Suggest stakeholders (you or others in your organization and other organizations) and participate in future interviews or focus groups.
2. Participate in the multi-stakeholder analysis of the associated requirements (e.g., outcomes, patient and payer populations, data expectations, reporting characteristics, and emerging capabilities) of the RWE environment.
3. Help identify and scope case studies to aid the design of a new RWE environment.

References

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