

Improving Healthcare Outcomes by Rewarding Value, NOT Cost

Featuring Industry Executive Insights







Introduction

A top priority for patients, payers, providers, and regulators is available, affordable healthcare. The medical products¹ industry is shifting from the traditional fee-for-service model to a fee-for-outcomes. Value-Based programs² are a key component of the transformation to outcomes-based models of care. They aim to provide:

- ▶ Better care for individuals
- Better health for populations
- Lower cost

A key challenge to achieving value-based healthcare is the misaligned incentives among constituents. For a medical product to earn a place on the US market:

Constituents	Top Concerns
Food and Drug Administration (FDA)	Proof of safety, efficacy, and security
Centers for Medicare & Medicaid Services (CMS)	Product is reasonable and necessary
Payers	Per member per month (PMPM) cost
Providers	Reimbursement rates

Recent efforts to improve the quality and transparency of healthcare go beyond these fundamental requirements to ask for **demonstrations of effectiveness based on real world evidence**, and performance within the constellation of products and services involved in an episode of care.

At the same time, ethical concerns impose greater restrictions on how manufacturers market their products and on their access to providers and other stakeholders.

Communicating product value propositions to potential customers grows more complicated all the time. It requires the availability and exchange of ever greater quantities of data, and more complex types of accurate, science-based information. It also requires control of the communications content across the entire lifecycle.

Different company departments – regulatory, reimbursement, medical affairs, marketing – perceive and select the information most relevant to their objectives and concerns. The

¹ Medical products include drugs, biological products, medical and diagnostic devices; and products that emit radiation.

² CMS Value Based Programs



messages these different groups create must be consistent and compliant with regulations and company policies. They must be modified or updated as new information is available or when circumstances change. Messages should be customized for different audiences – clinicians, patients, administrators, value analysis committees, payers, policymakers – and sometimes further tailored to the specific demographics, economics, and structure of an individual hospital or practice.

Managing this vast body of evidence is a difficult task. It must also be presented in an attractive and compelling manner because, after all, communication is telling a story that needs to engage the audience.

How has the process of communicating value to customers and other stakeholders changed in recent years, and what approaches are companies taking to adapt to the new environment?

This research examines the use of value-based communications to support the transition to fee-for-outcomes models of value-based healthcare.

Research approach:

To support this research, Axendia conducted a series of interviews with Life-Science industry executives who oversee or execute the communication of clinical and economic value of their companies' products to providers, payers, and other stakeholders. We have analyzed these first-hand accounts of new challenges in value communications and the strategies and technological solutions that can help adapt to rapidly growing evidence requirements.

Axendia thanks the following executives for their insights in this research report:

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The opinions expressed by research participants in this report represent solely the opinions of the individuals and may not and should not be attributed to their current or former employers.



What Is 'Value', Anyway?

"Historically, getting a pharmaceutical or diagnostic product to market has involved the "three hurdles" of safety, efficacy and quality," says Cynthia Doucet, President of OutcomeSynergy. "Then a fourth hurdle of value came into focus. Affordability is also considered as decision makers plan where to allocate limited amounts of money. Questions that arise include 'how do you quantify value?', 'for whom', 'how do decision makers decide?' and 'how can we communicate that value?"

Not long ago, sales reps could pitch clinical benefits and impressive new product features to clinicians, who had the power to demand that administrators buy them. In a fee-for-service world, items and procedures were added to a bill that was sent to a payer, who generally paid it.

In a value-based healthcare environment, hard data guide reimbursement, prescribing, and procurement decisions. These determinations are based on real world evidence and focus on demonstrating that a particular product delivers the best outcomes for a specific patient population at an appropriate cost.

Value-based purchasing programs (VBP) reward healthcare providers with incentive payments for the quality of care they provide to patients. CMS's <u>Hospital VBP Program</u> and the American Hospital Association's (AHA) its <u>Value Initiative</u> encourages hospitals to

- improve the quality of care and patient experience,
- reduce or eliminate adverse events,
- advance affordable care and promote value, and
- support policies that improve affordable care.

Healthcare Model

Fee-for-service

Items and procedures were added to a bill that was sent to a payer, who generally paid it.

Value-based

Based on real world evidence and focus on demonstrating that a particular product delivers the best outcomes for a specific patient population at an appropriate cost.

As a consequence, manufacturers seeking market access for a new product must generate ever-increasing quantities of evidence demonstrating value.

Michael Bershad, Manager of Global Health Economics and Reimbursement at Edwards Lifesciences, says that just in the past few years, he has seen a shift from simple outcomes to value: "true value, economic value, dollar sign value, clinical value."

What constitutes an acceptable value communication is not always clear, says Neeraj Iyer, Senior Director & Head, Evidence Synthesis & Value Assessment at Novo Nordisk. "The 21st Century Cures Act said that you can communicate the value of your product in the real world if it meets certain criteria and is communicated in certain settings. One of those criteria is called CARSE - competent and reliable scientific evidence. FDA³ has left it open for every company and its legal and regulatory groups to define what their comfort around CARSE is."

From a purely practical point of view, "value" has another meaning. "It's also value in the sense of importance," says Michael Bershad, Manager, Global Health Economics and Reimbursement at Edwards Lifesciences. "How do I elevate the solution that I am providing as being among the top 10 problems that the hospital administrator has? They're going to pick their top 10 at the beginning of the year, and everything else will be noise. How do I make sure that I am not noise?"

³ FDA's Guidance on Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities



Value evidence must also consider longer term downstream consequences of an earlier diagnosis or particular intervention.

"It's important to understand the perspective of your audience so that you can analyze and communicate the benefits and costs that matter to them most."

Cynthia Doucet,

President of OutcomeSynergy, Inc.

"You have a very well-defined bar from FDA on what you have to prove clinically: safe and effective. But it's that value that a lot of device manufacturers neglect to demonstrate. You would think that it would be painfully obvious, but companies think that their product is just going to fly off the shelves. I can count on all my fingers and toes the times that I've talked with a device inventor who has been sure that this was going to have immediate uptake, 80% market share immediately. And that just doesn't happen" says Doucet.

So Much Evidence, so Little Time

"What has not changed," says Max Iglesias, Director, Health Economics & Market Access at Johnson & Johnson, "is the availability of time. There might be a lot more evidence and a lot more means of conveying that evidence, but I'm not sure that surgeons or other stakeholders have a lot more time to digest that much more evidence. You cannot make your initial conversation very complicated. It has to entice further conversation."

The story must be the right one, and reps have not always had the information they need to succinctly convey the value proposition. Tina Ivovic, Vice President of Market Access at TransMedics, recalls her early years working on the provider side, where she ran revenue recognition and billing compliance. "I would meet with device manufacturers as a provider and ask them, 'What do you have for coverage, coding, and payment?' And a lot of them would say, 'Well, look at this shiny widget.' Great widget, let's talk about how it's going to get reimbursed. Even the Mayos of the world can't afford to adopt something unless it has an economic story."

TransMedics Value Story

Even the right value story may fall on deaf ears if a customer remains focused on immediate costs and discounts rather than the broader value picture. Ivovic's current company, TransMedics, markets an organ transfusion system that maintains donor organs for transplant longer than the cooler traditionally used for transport. At \$70,000, customers sometimes balk at the cost. With the device, more hearts remain viable for transplant longer, increasing the number of recipients and reducing wait times that consume healthcare dollars in supportive care. "We told our hospital customers this and some still respond, 'It's \$70,000.' I said, 'You're getting paid 100% from Medicare through the organ acquisition cost report payment. Payers want you to use this. They're willing to have a conversation and adjust your payment group for this.' 'Well, it's still \$70,000.' 'For every heart transplant, even from Medicare, you are making \$100,000 to your bottom line. You're doing 30 heart transplants now. You could do 70 next year. That's a lot of money to your hospital because you're doing this procedure. The length of stays are going to be shorter, the ICU, the complication rate is cut to a third of what it was."



It can be challenging to quantify and communicate the value of a specific medical product, particularly if its use is embedded within a constellation of other products and activities involved in a procedure or episode of care, even when the overall benefits seem clear. "It becomes a web of problems that really can only be addressed in a value story," says Michael Bershad, Manager, Global Health Economics and Reimbursement at Edwards Lifesciences. "It's no longer value messaging. It becomes a value story that you have to tell. And like any story, not only does it now have to be believable, but it has to resonate, and it has to be good."

Tina Ivovic, Vice President of Market Access at TransMedics, added "Hospitalizations for heart failure almost always lose money. You show a hospital: you're losing money on every heart failure hospitalization, and this tool keeps those patients out of the hospital. Use the tool so that you can use your bed days for something that's going to drive your revenue. That is another light bulb moment for the administration. Solve a problem they don't even know they have." Heart failure is a condition for which Medicare gives penalties and incentives.

"The BaseCase model was the best tool we could come up with so that you can say, 'Here's your population. Here's what your problem is. Here's how we can solve it. Here's what you're losing. Here's what you're gaining. You're worried about getting a 10% discount on this device. I'm worried about your 30% error rate that is causing you to lose revenue. So we're not going to give you the 10%. Instead, we're going to come in and we're going to fix the problem.' That's value."

Tina Ivovic,

Vice President of Market Access
TransMedics

Who Do You Even Talk To?

"There are many different audiences to consider – payers, physicians, patients, health systems, companies, etc. They all have different perspectives, needs, and definitions of what value means to them," says Cynthia Doucet, President of OutcomeSynergy, Inc. "It's both a science and an art to design a compelling value story. You have scientific evidence to start with, then you get a clear understanding of the audience. The next challenge is narrowing down the communication objective for that audience and planning a targeted discussion flow, which can potentially vary based on their input."

"For the clinicians, value is patient outcomes," says Michael Bershad, Manager, Global Health Economics and Reimbursement at Edwards Lifesciences. "For the department head, value is readmissions and ease of use and throughput. For the hospital administrator, value is patient outcomes because they're related to costs, length of stay, and complications that aren't paid for. The payer's value is all about PMPM {per member per month}. Does this affect PMPM? All of these things interplay and we have to start thinking about all of these different audiences."

It is difficult to reach the right people within a hospital to make what may be a complex value argument. According to Max Iglesias, Director, Health Economics & Market Access at Johnson & Johnson, "What we need to do is to arm them with the budget impact or the economic arguments that they need to use themselves to advocate internally. It is up to us to provide the arguments to the champions, so that they can articulate them."



But What Does It Mean for My Hospital?

"Too often a potential customer's response is, 'Not my data, I don't care', but when you can show them their numbers, they believe it more. This is your data. This is what's happening at your hospital. Yes, you are actually performing this way, and you can do better. We're not showing you a national average from a clinical trial of three hundred institutions. We're showing you your institution."

Michael Bershad,

Manager, Global Health Economics and Reimbursement Edwards Lifesciences

"When you make it personal for them, the message resonates better 100% of the time. And that's where we go to these dynamic tools. Because even when you show them their own data, they don't always believe it. They'll say, 'But my specific case is not like that. It's more like this:" Then it is useful to be able to input additional case-specific information. "That's where we start seeing these big wins, these aha moments. You can only get that from dynamic tools. You can't have that with old school paper presentations on a laptop screen" says Bershad.

Debra Miller, Associate Director of Sales Training & Digital Marketing at EHOB, which manufactures products for pressure injury prevention, says of potential customers, "They're asking for more robust information. Rather than simply one app, we're able to provide them with all of the videos, pressure mapping, clinical evidence, and even case studies. We use cases that demonstrate ROI for that specific facility. We have a hospital-acquired pressure injury calculator. Sales reps can input data based on the hospital's current prevalence rate or incident rate, what their target is, and how much they're spending on rental beds. We like to demonstrate a one-year and a three-year cost savings if they were to leverage some of our products. Sales reps can grab someone's attention and then be forwarded to the next point of contact. They love leveraging these calculators with the value analysis committee, because they're able to immediately demonstrate ROI. We're able to demonstrate cost savings and still play very nice, not referencing competitors. We developed it ourselves in the BaseCase platform.

The Challenge in the Field

The front line communicator of the value propositions a company creates is the sales rep calling on customers. The task of sales reps has grown more complicated, with increasing restrictions on hospital access and interactions between industry sales representatives and healthcare providers. Even with good access, sales reps need materials adapted to the situations where they make their pitch.

Companies generate vast amounts of marketing materials. "And those materials," says Michael Bershad, Manager, Global Health Economics and Reimbursement at Edwards Lifesciences, are used "when they're walking down a hallway, because that's the time they have with these clinicians. We're not at the administrator level, we're not in a boardroom. They're in their scrubs, walking from operating room to operating room. The reps have literally a minute to pitch an entire story. Are they going to start handing out pieces of paper that the clinician is probably going to throw away? Or are they going to show them something pretty and shiny and customizable? Any platform, not just BaseCase, has to be able to adapt real time and not be linked to a cloud. Because oftentimes, you're in a metallically shielded operating suite that doesn't get cellular reception because there's an MRI machine 10 feet away from you."



The Change to Digital Communication

Companies have used digital communication tools for years, but the COVID-19 pandemic, devastating in so many ways, wrought havoc with the traditional medical sales rep's or medical liaison's process and suddenly became the only way of interacting with customers. It was imperative to create messaging that was not only meaningful but engaging to audiences who could easily turn off something that did not hold their interest or address their real concerns.

"At first, there was really no interaction," says Erin Duffy, Medical Science Liaison at Merz Therapeutics.

"Eventually we got talking to them again and it was incredibly frustrating when you set up a video chat with a doctor who has limited time and it doesn't even work properly. Within that first five minutes, if it's not working, you have to ask if you can reschedule or try talking to them over the phone."

The exigencies of the pandemic hastened the use of a digital approach: "We launched BaseCase literally three weeks before everything shut down," says Debra Miller, Associate Director of Marketing at EHOB, "We were fortunate. Sales reps weren't able to go into the acute care facilities. It was new for them to have all of these virtual meetings. It wasn't new just for the sales reps. It was new for our key customer segments as well. But with a sales enablement platform like BaseCase, you're able to share your screen and walk them through any type of collateral – whatever they might need – clinical evidence, instructions for use videos, information to demonstrate the overall benefit of our product and why it should be brought into their facility. It was a huge game changer."

"Cloud-based materials relieve the reps' burden of deciding what materials to take on a particular call or remembering to find and send something afterward. "A rep doesn't even have to store stuff on their laptop."

Max Iglesias,

Director, Health Economics & Market Access Johnson & Johnson

"Your ability as an account to provide answers in the same meeting versus shortly thereafter has a huge value. Your responsiveness and the quality of your response goes a long way in continuing a relationship. Why wouldn't that account reach out to a Novo Nordisk representative the next time they want to find out something about a key clinical formulary decision? Or if they have a quick thought, 'Hey, I'll probably call Jane Doe from Novo' instead of calling the rep from that other company."

Neeraj lyer,

Senior Director & Head, Evidence Synthesis & Value Assessment Novo Nordisk.

"I think of successful interactive value messaging as Evidence with Elegance. It's built on a sound scientific foundation, is transparent and straightforward, and ideally can help audiences consider potential benefits in their own scenarios. Outstanding technology is needed for interactive messaging, and is already available. The technology should also be elegant and trouble-free, allowing your dynamic content to be the focus of compelling discussions with decision-makers."

Cynthia Doucet,

President

OutcomeSynergy, Inc.



Do It Yourself / No Code Solutions

Focus on your message

"In a Decision Analysis evaluation I was involved with for 'Interactive Value Messaging,' the chosen solution was BaseCase. It was a good match for the team's needs, including:

- design with drag-and-drop,
- Excel model integration,
- update distribution (users receive approved content updates automatically the next time they sign on),
- online or offline use,
- · user management (including an option for single-sign-on with an existing directory) and
- other needed capabilities.

It was also helpful that BaseCase is a cloud-based app so there was no need for the company to build or maintain server infrastructure for this initiative.

Over 10+ years, dozens of value messaging initiatives and interactions with thousands of users, I've come to believe that a true benefit of a product like BaseCase is that it frees you up to focus on your message. If you have a solid foundation that solves the technical hurdles around creating, distributing and maintaining the interactive app, your team can have a laser focus on creating compelling evidence-based 'Aha! moments' for your customers."

Cynthia Doucet,

President OutcomeSynergy, Inc.

In the past, the production of educational and marketing materials was often outsourced to external vendors or, at larger companies, referred to internal communications and design departments. Outsourced value communication materials took time – to educate the vendor on the product and message, to go back and forth on wording and design, and to make changes when necessary. Time also translates into cost.

"It took three months each, maybe more, to just create and reroute every revision," says Tina Ivovic, Vice President of Market Access at TransMedics, of the old process of creating videos and other materials, "And sometimes you would go back to the original one.""

"A major benefit of sales enablement platforms, especially BaseCase, is that they will allow your marketing team to go in and develop their own content," says Debra Miller, Associate Director of Marketing at EHOB. "Previously we had to outsource that. Now we have a sales enablement platform that allows any marketing person to be trained and they can make their own edits."

Many technologies have been used to communicate marketing messages, clinical information, or customized value propositions, from slides presentations to spreadsheets, forms, or web sites to more sophisticated sales enablement tools. They can all be effective, but, remarks Cynthia Doucet, President of OutcomeSynergy, Inc., they "present challenges when you try to manage your content moving forward."



Doucet says, "If you inherited a spreadsheet that your predecessor sent to multiple people,

- How do you know who has access at this time?
- Can you make any needed changes yourself or is a consultant needed?
- ► How do you distribute updates or corrections?
- Can you confirm that only the latest approved version is being used?"

"I could just make a change and push it out," says Max Iglesias, Director, Health Economics & Market Access at Johnson & Johnson, who uses BaseCase. "Next time somebody opens the app in their iPad, it reflects those changes. So technology allows people to have access to the latest, and only the latest."

An additional benefit, says Debra Miller, Associate Director of Marketing at EHOB, is that "we don't necessarily have to go through the full content approval process again. We would let clinical or medical affairs know that this change has been made, send a screenshot. They look at it, and everyone signs off, It really expedites the process for revisions and the whole content approval process."

But You Can't Say That!

Operating in a regulated environment imposes limits on what company representatives can say to customers. At the same time, ethical concerns have imposed greater restrictions on how manufacturers market their products and on their access to providers and other stakeholders.

"You may have different framing of the content for different audiences," says Neeraj Iyer, Senior Director & Head, Evidence Synthesis & Value Assessment at Novo Nordisk, "But one cannot veer off the path too much. There are systems in place to make sure that no one crosses the line by saying something which is not what is in the research study. The account teams know best how to present the information and how to frame it. In-house teams need to make better efforts to understand the customer, be knowledgeable about the guardrails, responsibly interpret the science and trust the customer facing teams that they know the best timing and best framing of your evidence."

Michael Bershad, Manager, Global Health Economics and Reimbursement at Edwards Lifesciences, agrees. "That is where platforms like BaseCase, Salesforce.com, what have you, are really important. I can lock certain features but enable others. Before, when you hand them a PowerPoint slide, I don't know what they're doing with it. I don't know what they're changing. If now that PowerPoint is embedded in a tool where they can't manipulate it, they have to present it. Maybe they can customize which slides they present, but they can't make changes to my slides. I think technology can help us keep our company safe. Technology like that can help us keep everybody walking that fine line between compliance and sales."



How Do You Know If It Works?

Much time, effort, and expense go into creating materials for marketing, medical affairs, and others who represent the company and its products to providers, payers, and other outside audiences, but even the best materials are only as useful as they are actually used. As in developing products themselves, it is helpful to know what works, what doesn't work, and what might make things better or more appealing or easier to use, which is only possible if there is feedback on something's performance.

"We need a consistent flow of good science, balanced interpretation, and timely availability of evidence," but we also need to track what's working and what's not. End of the day, if this were my business and I was investing my own money in this one, I would like to know what the return on investment has been."

Neeraj Iyer

Senior Director & Head, Evidence Synthesis & Value Assessment Novo Nordisk

Max Iglesias, Director, Health Economics & Market Access at Johnson & Johnson, who uses the BaseCase system, remarked, "One of the things I loved when I adopted it eight years ago or so is that I was able to track who was doing what. Not to punish or to reward, but to understand what's working or what wasn't, and whether training was required."

Michael Bershad, Manager, Global Health Economics and Reimbursement at Edwards Lifesciences, says, "We know how many times things have been pulled out and requested. Every time a rep downloads something, we get a hit, and we know. If something has never been pulled out of either warehouse, we know that it's a useless tool, and we have to go and figure out why. And as I continue to evolve the message and craft it and hone it, these things become really important. If they clicked on button A fifty times and button B three times, I really need to start paying attention to button A. I can eliminate B, and make the message simpler. I will ask the person with the most presentations in a given month to tell me some success stories. I'll ask the person that opened it for the shortest amount of time what happened; why didn't this work out for you?"

Cynthia Doucet, President of OutcomeSynergy, Inc. elaborates further on the value of analytic tools and credible metrics in contrast to the purely impressionistic and anecdotal – and too often inaccurate or wholly absent – past methods of monitoring messaging effectiveness. "Current technology allows opt-in usage tracking, so you can better understand how many people are using your app, how long they stay on each page, and even which buttons or controls they interacted with. You may also have the capability of collecting information provided during the discussion, again with appropriate agreement from the viewer, so there may be opportunities to better understand your customer's needs through this analysis. As teams work to understanding app value, technologies like BaseCase can be incorporated in creative ways such as automated post-use questionnaires, data exports, or even live data connections to sales management systems."



Conclusion & Recommendations

The decision to adopt a new medical technology is based on evidence of both clinical and economic value. It is a complex process involving multiple stakeholders with differing objectives and criteria.

- Manufacturers must draw data from multiple sources and integrate it into a compelling story, often customized to the specific characteristics of an individual provider organization.
- Being able to respond quickly and accurately to customer questions and concerns is vitally important.
- Care must be taken to ensure that all materials comply with regulatory and company policies.
- Communicating product value propositions to potential customers grows more complicated all the time and requires the availability and exchange of ever greater quantities of data and more complex types of accurate, science-based information.
- Controlling communication content across the entire lifecyle is a key requirement.

As a result, the use of versatile digital technologies that communicate messages succinctly and can be adapted to customers' work environments provides a tremendous advantage.

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Axendia is a leading analyst and strategic advisory firm focused exclusively on the Life-Sciences markets. The company provides strategic advice that enables its clients to prepare for, adapt to and overcome disruption. Axendia conducts primary quantitative and qualitative research that clients leverage to support their strategies and enables them to make informed decisions based on their unique needs. Industry stakeholders and regulators have relied on Axendia for trusted advice on Business, Regulatory and Technology issues and trends based on trusted sources. Axendia serves the entire Life-Science ecosystem ranging from startups to Fortune 100 companies including: Life-Science Organizations, Technology & Service Providers, and Regulatory Agencies.

Axendia is recognized as a Top 10 Analytics Consulting company by Pharma Tech Outlook and as a one of the 20 Most Promising Life Sciences Technology and Services providers by CIOReview.

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