

By Denise Myshko



The Evolution of the MSL

The changing healthcare system means the role of medical affairs and medical science liaisons must change and adapt to meet the needs of providers.

Gaining access to healthcare providers and key opinion leaders has become a key challenge for pharmaceutical companies. In the past, a pharmaceutical company's success was often determined by the extent its salesforce could access primary care physicians. While the sales representative is still a vital part of the process, medical affairs professionals have taken charge of scientific engagements with healthcare decision makers.

The core role of the medical science liaison is to be the key public resource for pharmaceutical companies to provide scientific and clinical expertise. These professionals work throughout a product's lifecycle, help to ensure that products are used effectively, serve as scientific peers and resources within the medical community, and are scientific experts to internal colleagues.

The MSL role, first established by Upjohn Pharmaceuticals in 1967 as a response to the need for scientifically trained field staff, is now vital to the success of companies both large and small.

MSLs bring value to companies that are commercializing their first product, as well as to established companies bringing new

FAST FACT

MSL TEAM SPENDING MAY BE AS MUCH AS \$5 MILLION IN THE UNITED STATES.

Source: Cutting Edge Information

commercial entities to market, particularly if they're in a new therapeutic area, says John Corcoran, founder and president, Trinity Partners.

"Later-stage companies need to transition from a heavy scientific medical orientation to develop this new capability of commercialization," he says. "MSLs can help companies bridge this gap."

The number of MSLs is expected to grow 20% in the next few years, according to a recent survey by the Medical Science Liaison Society. A big part of this increase in numbers is because CROs, medical device, diagnostics, and veterinarian companies are incorporating

the MSL role into their operations, says Samuel Dyer, CEO and chairman of the Medical Science Liaison Society.

"KOLs are demanding time with MSLs," he says. "For veterinarian medicine and device and diagnostics, MSLs have become such a vital component to the success of companies. The people they are engaging with externally, the KOLs and providers, are demanding time and are giving them time."

In fact, KOLs are willing to spend 45 minutes with an MSL vs. just two minutes with a sales rep, according to a recent survey by the MSL Society.

"It's clear that sales reps are still very important to pharma companies," Mr. Dyer says. "It's also clear that the traditional commercial model is gone — meaning the idea of having hundreds of thousands of sales reps globally is going away. How reps are being used is going to evolve."

In the past, interactions were very healthcare practitioner focused; now companies are also dealing with different individuals and organizations from a scientific perspective, says Michael Vredenberg, Ph.D., senior director of field medical affairs, Teva.

As the dynamics have changed in the marketplace, the ability to have a two-way communication and a true peer-to-peer exchange is more valuable than ever to key opinion leaders, physicians, and payer audiences.

DR. EVAN DEMESTIHAS
TMAC



“Healthcare is changing and, therefore, our interactions need to change,” he says. “Healthcare is substantially different from what it looked like 10 years or 20 years ago. Therefore, there needs to be significant changes in how we operate to stay with the times and make sure that we’re meeting the needs of the community.”

Evolving Role of MSLs

Industry experts say the role of the MSL is changing as larger healthcare trends impact the development of new therapies. Today’s therapies require highly specialized conversations with physicians and key opinion leaders.

This requires scientifically trained individuals who can be a resource for physicians to provide all the information that they need in order to better treat their patients. MSLs provide a link to the clinical trial information, as well as real-world data analyses.

Mr. Corcoran says many drugs approved today are novel therapies, treat orphan diseases, or are targeted therapies.

“These therapeutic categories are more complex and technical so they require people with scientific and medical expertise to help seed the market and to help develop the market,” he says. “This is why MSLs are becoming more and more important.”

Mr. Corcoran says if the nature of approvals continues with more complex and technical therapies, there will continue to be deployment of MSLs in tandem with sales reps on the commercial side.

“We’re also likely to see MSL deployment in the earlier stages of clinical trial development,” he says. “They may even be called clinical trial specialists, but they’re essentially MSLs. And while MSLs are not typically used in outcomes-related conversations explicitly, they may in the future be called to discuss outcomes and pricing because of the changing nature of approvals for small patient populations. MSLs, directly or indirectly, have an important role in these types of dynamics.”

This larger trend of developing more complex therapies is also leading to an evolution of MSL teams that will include outcomes or managed care liaisons.

“One of the key characteristics of that evolution is the number and diversity of the external stakeholders that the MSLs are asked to interact with,” says Raul Perez-Olle, M.D., Ph.D., executive director, medical affairs, Lexicon Pharmaceuticals. “In the past, MSLs were more focused on interactions with physicians who had research interests or who were part of academic centers. Now, the type of physicians who MSLs reach out to depends on the specific disease area.”

He says the MSL reach is also extending to other clinical stakeholders such as pharmacists and nurses, as well as payers, patient advocacy groups, and scientific societies.

Lexicon employs 10 full-time MSLs to support Xermelo, which received FDA approval in February to treat carcinoid syndrome diarrhea, a rare and debilitating condition that affects people with metastatic neuroendocrine tumors.

What Makes an MSL Successful

SCIENTIFIC AND TECHNICAL EXPERT

- ▶ Scientific expertise
- ▶ Presentation expertise
- ▶ Analytical thinking
- ▶ Business acumen
- ▶ Regulatory expertise

RELATIONSHIP MANAGER

- ▶ Customer focus
- ▶ Responsiveness
- ▶ Proactivity
- ▶ Solutions orientation

EXCELLENT COMMUNICATOR

- ▶ Communications clarity
- ▶ Building partnerships
- ▶ Value demonstration
- ▶ Influencing/persuasion
- ▶ Emotional intelligence

Source: MSL Society

“Prior to launch, the team worked on educating our external stakeholders, primarily physicians, nurses, pharmacists, and patient advocacy groups,” Dr. Perez-Olle says. “The focus was on the disease state and the burden of disease. They also focused on the data from our clinical trial program for Xermelo, making sure that everyone understood the clinical profile.”

Dr. Perez-Olle says a key role of the MSLs is bringing insights back to the company.

“Through scientific exchanges with physicians, thought leaders, and scientific experts, MSLs bring a lot of information and insights back into the organization that’s critical for the medical affairs plan and informing other functions within the company,” he says.

The deployment of MSLs allows for a two-way conversation with providers, says Evan Demestihias, M.D., worldwide head of TMAC, Parexel. (Editor’s Note: The Medical Affairs Company was acquired by Parexel in February 2017.)

“As the dynamics have changed in the marketplace, the ability to have a two-way communication and a true peer-to-peer exchange is more valuable to key opinion leaders, physicians, and payer audiences,” he says.

Over the last few years, there has been a need for even more specialized field-based medical roles.

There may be a very distinct correlation between the success of a salesforce in the field and the success of its counterparts in medical affairs.

NEIL GRAY
inVentiv Health



“We are seeing a greater demand for specialty liaison roles including clinical trial liaisons primarily supporting clinical sites to enhance patient enrollment, clinical specialists that focus more on tier two and local physician audiences and managed outcomes liaisons engaging with payers and integrated delivery network audiences,” Dr. Demestihias says.

He attributes this to the demand for MSLs to engage with multiple stakeholder audiences that influence the uptake, utilization, and impact the access of companies’ products.

“The classic MSL of the past cannot interact effectively with all of these distinct stakeholders in an efficient manner to achieve this multitude of desired outcomes,” Dr. Demestihias says.

Field-based knowledge workers are going to be in very high demand in the industry, predicts Neil Gray, senior VP, medical affairs, inVentiv Health Therapeutics Institute, a part of INC Research/inVentiv Health.

“We will see more emphasis on adding headcount on the health outcomes and community liaisons sides so organizations can speak intelligently not only on the science but on the economics of their medicines, and their support of advocacy groups” Mr. Gray says. “There is a need to instill a higher degree of business acumen into the MSL role. There may be a distinct correlation between the success of a salesforce in the field and the success of its counterparts in field medical.”

Dr. Perez-Olle points out that even in smaller companies such as Lexicon, MSLs are asked to support educational initiatives with payers and health economics and outcomes research.

“Originally, these functions were not at the core of the MSL role,” he says. “In companies such as ours with a smaller footprint and a smaller team size, instead of having a separate team, we ask our MSLs to develop the knowledge and competencies in health economics and outcomes research so they can support these initiatives.”



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JOHN CORCORAN
Trinity Partners

Future Role of MSLs

As the MSL role continues to evolve, especially in the use of technology, Dr. Perez-Olle says it will be important for these professionals to be able to engage in their activities through multiple channels.

“Traditionally, the most common form of interaction has been the one-on-one scientific exchange,” he says. “As we have a broader segment of stakeholders who we need to educate and interact with and as other channels to reach out to our stakeholders becoming more critical, we’ll definitely have to train MSLs with the necessary skills to use these multiple channels.”

Physicians are more amenable to having technological/virtual interactions and they are more accustomed to using channels such as Twitter, and they are engaging via virtual platforms where there is an opportunity for face-to-face interactions, Dr. Vredenberg says.

Teva, he says, is looking at virtual reality to give a better appreciation and understanding of clinical and/or mechanism type of information and data to its different customers.

The company has an early pilot program that is using 3-dimensional technology to illustrate a drug’s mechanism of action and the pathophysiology of a disease state.

Teva also is investigating the use of virtual reality to help physicians understand patients’ experience with neurological disorders, for example, what it might be like for someone who has Huntington’s disease to button his or her shirt.

“3D and virtual reality offerings help people to better grasp the mechanism of action of therapies, which is becoming more important as we as an industry are trying to better understand how certain diseases and disorders affect patients’ daily lives,” Dr. Vredenberg explains. “I can see artificial intelligence being applied in cases where we have computer algorithms that are addressing questions as a first line of defense, prior to human beings being involved.”

Behind the MSL Evolution

Part of what is driving the MSL evolution is a transfer of investment dollars from the large, relatively undifferentiated salesforces of the past to a much higher level of specialists who have scientific expertise and a higher level of skill focused on payers and providers, says Josh Schultz, senior VP and worldwide head of Parexel Access.

“There has been a shift to providing value in a more robust way than in the past,” he says. “The MSL function has gone from a marketing support function to a science-based one, and this is leading to different variations of the role. Additionally, payers have become essential gatekeepers. While MSLs have not traditionally called on payers directly, some specialty MSL roles are evolving to have these conversations with the payers or with the KOLs who influence the payers.”

Teva’s Dr. Vredenberg says payers are much more influential in making decisions about patient access to medications than ever before.

“It’s important for medical affairs and field medical staff to be engaged with payers so these decision makers understand the clinical value as they are making their evaluations on coverage,” he says.



By Kate Perry, MSc, PsychD
Director, Behavioral Science



Using Health Psychology to Design Patient Support Programs

Everyday, hundreds of people choose to not take their medication. How can pharma create patient support programs (PSPs) to help change unhealthy behaviors around treatment nonadherence?

We believe the answer lies in the application of **health psychology**, a broad discipline that focuses on understanding the psychology of patients and its influence on behaviors relating to health and illness. Although a relatively young specialty, the literature is already vast. There are more than 80 behavior change theories that help us understand and predict health behavior change, as well as descriptions and evidence to support the use of 100+ behavior change strategies.

Unlike other disciplines that are theoretical and largely academic, health psychology has a very practical side, allowing us to apply learnings to the design and execution of PSPs. Navigating the field, however, needs a specialist that understands how to apply theoretical frameworks and research findings to real world settings.

Our global health psychology experts translate and apply their science in two important ways:

- ▶ **To understand the reasons behind nonadherence.** Recognizing the “why” behind behavior is a first step to identifying support areas to make behavior change interventions personal to an individual. A person’s nonadherence could be based on perceptions of their treatment and disease (“I don’t need this - it’s not serious”), practical barriers (“I can’t get to the pharmacy”) or lack of social support (“It’s hard to talk with my doctor”).
- ▶ **To build content that is effective at changing behavior.** After seeing what beliefs are driving behaviors, we can then select appropriate behavior change strategies and craft custom messages to precisely address individual barriers. This personalization is key to helping interventions be effective at changing behaviors for the long-term.

Once we get these aspects right, the application of health psychology works regardless of the disease state, treatment type or communication channel. Consider these examples:

To increase adherence to an asthma preventer medication, our health psychology team designed a PSP that used **customized SMS/text messages**. Early research helped us understand individual barriers to adherence so each person could be targeted with relevant messaging via texts on their phone. The result? A 15% lift in adherence rates that was sustained once the text program ended.

For people prescribed a second line treatment for cancer, we created a PSP grounded in a **clinical nurse educator network**, delivering customized messages to each patient during one-on-one counseling at home visits and by phone. Patients enrolled in the program stayed on the drug 2½ times longer than those not enrolled.

Learn more about our use of health psychology for behavior change at: www.atlantishealthcare.com

Dr. Vredenberg adds that in the future physicians will be accountable for patient outcomes.

“They’ll need to understand real-world evidence and they’ll need to understand outcomes data associated with different drugs and products,” he says. “MSLs are engaged right now in making sure that HCPs understand the clinical value and outcomes data associated with products.”

Dr. Demestihis says this is largely a trend among larger companies, and some smaller companies with limited budgets may implement a more specialized MSL team because of the nature of the product.

“A driving force over the last half-dozen or so years has been the limited access that sales reps have in front of key physicians and other stakeholders such as payers who can move product,” he says. “With the limited amount of time that practitioners have, they want to spend it as productively and as effectively as they can. An MSL has the academic training and background to provide in-depth clinical information, which leads to a much more complete and effective interaction.”

Measuring the Impact of MSLs

Measuring the impact of the MSL, Mr. Gray says, involves a blend of quantitative and qualitative metrics.

He says MSLs need to be able to communicate and synthesize information to create new data sets from across a wide range of inputs, teach, and listen. There are about 12 to 15 consistent measures that drug companies and support companies use to measure the quantitative success of a MSL, such as: how many visits the MSL has, how long the visits are, how many clinical or market pearls are picked up in conversation, the strength and depth of the working relationship with a key opinion leader, the increased level of engagement with the thought leader, if the KOL wants to be a speaker or author for the organization, whether the KOL wants to sit on an advisory board, or if the KOL wants to contribute knowledge from either his or her research or general knowledge in terms of contacts with other peers throughout academia.

Mr. Corcoran says CRM tools can help, but he stresses that traditional, quantitative metrics don’t hold up for MSLs.

“It’s generally not appropriate to measure MSLs using metrics that are more typical in the commercial side,” he says.

Dr. Demestihis agrees that the impact of medical affairs cannot be measured the same way that traditional sales or marketing activities are or have been measured.

“From a qualitative standpoint, we measure feedback that comes directly from the physicians, the pharmacists, and the healthcare practitioners about their interactions,” he explains. “Feedback can also come from MSLs’ sales counterpart colleagues.”

Mr. Corcoran says it’s important for these specialists to begin speaking with KOLs early on in a product’s development.

“Even for companies that may be headcount or budget conscious, there are ways to deploy MSLs selectively and creatively without adding substantial cost,” he says.

Dr. Demestihis says as a general rule, companies should begin engaging MSLs 12 to 18 months before the expected product launch.

“For a novel product that might be a new therapeutic entity, more education needs to occur so the earlier the deployment the better,” he says. “For products that might have some incremental benefit but aren’t as dramatic as a new molecular entity, then we recommend deploying MSL teams six months before launch. Ideally, prelaunch is the time to have MSL teams go out and begin to speak about the exciting research.” 