

**A Qualitative Study:
Clinical Marketing Strategies for Medical Devices Innovations that
Increase Adoption in the USA**

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ABSTRACT

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The medical device industry is a prominent and lucrative industry in the USA that benefits the country by both improving health and improving the economy. As this industry is heavily regulated, marketers in the medical device industry are faced with unique challenges. Unfortunately, due to the nature of this industry, marketing strategies pertaining to medical devices are often over-looked by researchers and scholars. The purpose of this research is to gain insight and better understand the importance of two key clinical marketing strategies employed by medical device companies: key opinion leader (KOL) strategies and evidence-based medicine (EBM) strategies. Nine medical device companies that market medical device innovations were interviewed regarding these two strategies and how/if they have contributed to the company's success. The results were analyzed so patterns and similarities linking these strategies to measures of success could be examined. The results suggested that a KOL strategy is highly important and always used and that companies that pay their KOLs are more likely to have sales. In order to attract and recruit KOLs, the most used strategies included networking and requesting references. The interviews also revealed that KOLs are likely to pay for products, unless they are researchers in an academic setting. With regards to EBM strategies, the interviews indicated that an EBM strategy is not always necessary to achieve sales. Further, the interviews indicated that employing a KOL and EBM strategy may leverage other strategies. When measuring success, the interviews indicated that sales were a key indicator of success. Lastly, early stage companies are less likely to have sales than mid-late stage companies and companies with niche products are more likely to have sales and less likely to employ an EBM strategy.

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INTRODUCTION

The healthcare system in the United States continues to face increasing costs despite government interventions and policies. Now, more than ever, it is important to nurture the development of medical device innovations, which will ultimately provide faster, cheaper, safer and more efficient patient care.

The mix of modern technology and medicine has led to substantial advances in the health outcomes of people around the world.¹ Notable advances include pacemakers, dental lasers, automatic defibrillators (AEDs), cochlear implants, robotics in surgery, prosthetic hearts and cardiac stents. These medical device innovations present a profoundly new opportunity for both physicians and patients.^{2,3} Given the tremendous historic, and potential future, impact of medical device innovation on healthcare in the United States, it is critically important to better understand the characteristics of these innovations, particularly marketing strategies, that will undoubtedly ensure their success in the marketplace.

The purpose of this research is to gain insight and better understand the importance of two key clinical marketing strategies employed by medical device companies: key opinion leaders (KOL) and evidence-based medicine (EBM). By better understanding the impact of these strategies, medical device marketers can construct effective marketing strategies that will be guided by tested and proven methods. The results of this study will

inform strategic decisions and therefore will be important to companies that are developing marketing strategies for medical device innovations.

Literature Review

Medical Devices

Medical technology products are ‘medical devices’ which cover “any instrument, apparatus, appliance, materials or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease or an injury or a physiological process”.⁴ Medical devices are extremely important, as healthcare delivery and advancement would not be possible without them. In 2006, the global medical market reached \$209 billion⁵, however the United States (USA) is the largest medical device market in the world with a market size of around \$110 billion, and it is expected to reach \$133 billion by 2016.⁶ To put this number in perspective, the USA is home to more than 6,500 medical device companies, mainly small and medium-sized enterprises (SMEs), making it one of the country's largest industries and exports. According to the Food and Drug Administration (FDA), 4,262 medical devices were released into the US market in 2002.⁷ In addition to the clear economic importance of medical devices, these products are essential in reducing healthcare costs and increasing patient welfare.

Medical devices are heavily regulated in the USA and most other parts of the developed world. In the USA, the FDA is the governing body that regulates, among other things,

medical devices. The FDA has established classifications for approximately 1,700 different types of devices and grouped them into 16 medical specialties. These 16 medical specialties are as follows: Anesthesiology; Cardiovascular; Chemistry; Dental; Ear, Nose, and Throat; Gastroenterology and Urology; General and Plastic Surgery; General Hospital; Hematology; Immunology; Microbiology; Neurology; Obstetrical and Gynecological; Ophthalmic; Orthopedic; Pathology; Physical Medicine; Radiology; Toxicology. Each of these types of devices can then be classified to one of three regulatory classes based on the level of control necessary to ensure the safety and effectiveness of the device. The three classes and the requirements are as follows:

- Class I (General Controls)
 - With Exemptions
 - Without Exemptions
- Class II (General Controls and Special Controls)
 - With Exemptions
 - Without Exemptions
- Class III (General Controls and Premarket Approval)

While “medical device” is a rather broad term, it can be further segmented into “medical device innovations”. The main difference being that medical device innovations are produced by knowledge gained from scientific research or by overcoming an engineering problem (i.e., applying existing knowledge to new problems). Typically, patents are used to measure medical device innovation. A medical device innovation is differentiated from a general medical device based on the following parameters:

- It is not medical supplies or disposables
- The product is new and innovative (i.e., serves a new use)
- An innovation is defined as any product, idea or practice that is viewed as new by an individual or the adopting unit ⁸
- Interacts with a person's physiology
- Science-based
- Class II or Class III

Additionally, the following can identify medical device innovation⁹:

- Based on engineering problem solving by individuals or small enterprises
- Incremental rather than radical
- Rarely depends on results of long-term scientific research
- Does not reflect the recent graduation of fundamental knowledge

In order for medical innovations to be successful, they must solve an unmet medical need or reduce healthcare costs. Otherwise, adoption will not occur. It is important for the user and/or the buyer to understand how a medical device innovation will either reduce costs or increase care – preferably both. In order for this message to be adequately delivered, companies rely on effective marketing strategies.

Marketing Strategies

Marketing strategies are critical to the success of any company. As defined by David Aaker: “a process that can allow an organization to concentrate its resources on the

optimal opportunities with the goals of increasing sales and achieving a sustainable competitive advantage.”¹⁰ Marketers in all industries are faced with various hurdles; however, marketers in the medical device industry face novel and unique challenges.¹¹ This could be because the medical device industry is heavily regulated, the purchasing decision is based on multiple factors (i.e., safety, efficacy, efficiency, politics) and marketing requires a combination of medical, scientific and business knowledge.^{12,13} Innovative medical devices require specific and focused marketing strategies that are unlike most other newly released products. Therefore, it is important for medical device companies to embrace tested and successful medical device marketing strategies in order for their innovations to be adopted by the medical community.

There are numerous factors that have been shown to increase customer acceptance/buy-in of medical innovations including (but not limited to): evidence for clinical benefits, economic benefits and increased patient welfare; product safety; transfer of evidence into clinical practice (e.g. clinical guideline development); and expanding product use to new indications. Medical device companies heavily rely on marketing strategies to increase adoption; however, due to regulations and the very nature of the medical devices, marketing strategies in this industry are very different from standard industries, say, consumer products. Much like the entertainment industry¹⁴ and the high-tech industry,¹⁵ marketing in the medical device industry requires specific knowledge and strategies. Marketing strategies used by medical device companies include advertising,¹⁶ digital/social media,¹⁷ awards/recognition,¹⁸ exposure through trade shows and exhibits,¹⁹ direct marketing via a savvy sales team, key opinion leader (KOL) programs²⁰ and evidence-based medicine (EBM) strategies.²¹

In the literature, two clinical marketing strategies were notably more prominent. These two strategies were a Key Opinion Leader (KOL) strategy and Evidenced-Based Medicine (EBM) strategy.^{22,23} Key opinion leaders are a source of information, influence and an important determinant of adopting or avoiding new treatments. It is widely believed in the industry that physician-led peer review of new medical technology is the top best practice when making purchasing decisions.^{24,25} Evidenced-based medicine emphasizes the use of evidence from well-designed and conducted research in healthcare decision-making. This strategic marketing tactic has been known to increase customer adoption and market penetration.²⁶

Key Opinion Leader (KOL) Strategy

The term “key opinion leader” was coined in 1955 by Katz and Larzarsfeld when they described an individual’s decision-making process.²⁷ Since then, the term has been widely accepted as a marketing principle. The profound influence of a person’s peers on behavior and decision-making has been well documented throughout social psychology literature. For many years, marketers in many industries have taken advantage of this psychological principle in order to boost sales. It is no surprise that this phenomenon transcends to the medical device industry. A key opinion leader (KOL) (also known as an opinion leader, thought leader or product champion) has been identified anecdotally and in the literature as a critical factor related to adoption of medical device innovations. Studies related to innovation diffusion in medicine dating back to 1966 identified the physicians association with opinion leaders as a source of information, influence and an

important determinant of the adoption or avoidance of new treatments.²⁸ More recently, a 2013 Deloitte annual survey²⁹ of U.S. physicians revealed that 70 percent of U.S. physicians believe that physician-led peer review of new medical technology is the top best practice when making purchasing decisions. In fact, studies have found that every local medical community has a small group of easily identifiable physicians who are influential in facilitating new learning and adoption of new medical products; these opinion leaders are looked up to by their colleagues for advice and unbiased information.³⁰

When attempting to understand medical KOLs, they can be sub-divided into “market leaders” and “clinical leaders”. Market leaders are tightly connected to the local patient and physician communities. They are typically general practitioners with large practices who gain recognition through the satisfaction and loyalty of their patients. According to “Best Practices”, a leading benchmarking, consulting and advisory services firm serving biopharmaceutical and medical device companies worldwide, KOLs' have “proven to be among of the most effective and critical means of building product awareness in the medical and scientific communities.”³¹ Clinical leaders are well-respected experts of a specific disease or therapy with a strong reputation. This reputation is typically strengthened by the number of publications they have and the rankings of the medical journals in which those articles are published in. Their roles vary, but often times clinical leaders are usually involved in bench testing the product before it goes to market. It is thought that market leaders have a greater impact on general practitioners' behaviour than clinical leaders, while clinical leaders have a greater impact on hospital-based physicians' behaviour than market leaders.³²

Evidence-Based Medicine (EBM) Strategy

Evidence-based medicine (EBM) has become a “buzz word” in the medical arena. For medical device companies, it has become increasingly important for survival in this competitive industry. Generally speaking, EBM uses thorough, well-designed research studies and empirical evidence to optimize decision-making (i.e., purchasing decisions). In the medical device industry, EBM primarily focuses on a product’s efficacy and effectiveness. Clinical efficacy is proven when there is evidence that the medical device is beneficial when used by experts in a research setting.³³ Clinical effectiveness is proven if there is evidence that the medical device is beneficial when it is used by a representative sample of physicians in a normal clinical setting.³⁴ This clinical marketing strategy is a tool used to optimize product introduction, adoption, life cycle management and business development of medical device innovations.³⁵ The key objective of this strategy is to support customer adoption and market penetration of the medical device. Unlike the pharmaceutical industry, in which product development is largely based on the development of strong clinical evidence, medical devices do not necessarily follow the same product development pathway.

Additionally, newly launched medical devices are not always accompanied by clinical or economic evidence to support the product’s effectiveness. Often times this will negatively impact the company’s commercial strategy because there is insufficient data linking the use of the product with a relevant clinical benefit in order to convince a clinician or a hospital manager of the advantages of this new medical device.³⁶ It’s

preferable to launch a product that has the appropriate clinical data to support a well-defined marketing strategy.

Indicators of Success

There are many different ways to measure the success of a marketing strategy. Common indicators include sales/revenues, net income, devices deployed, rate of adoption and market penetration. Each company must work with management to develop indicators/benchmarks of success and ways to reach those goals. A major factor in the success or failure of a marketing strategy at any level is whether it fits in the market environment and if the offering meets the requirements of potential customers. Today's marketing goal is not only to increase market share, profitability or gain further customers at the expense of the direct competition, but also to have a long-term strategic partnerships.^{37,38}

When looking at high-tech products, such as medical device innovations, rate of adoption and market penetration are often used to define the company's success.^{39,40} Rate of adoption is the speed at which innovation is adopted (the adoption curve). Rate is usually measured by the length of time required for a certain percentage of the members of a social system to adopt an innovation.⁴¹ The rates of adoption for innovations are determined by an individual's adopter category. In general, individuals who are considered early adopters require a shorter adoption period when compared to late adopters. Market penetration is a measure of brand or category popularity. It is defined as the number of people who buy a specific brand or a category of goods at least once in a

given period, divided by the size of the relevant market population.⁴² Additionally, market penetration occurs when a company penetrates a market in which current or similar products already exist. The best way to achieve this is by stealing customers from competitors.

Hypotheses

This research intends to assess the validity of two widely adopted clinical marketing strategies: Key Opinion Leader (KOL) strategies or Evidenced-based Medicine (EBM) strategies. I hypothesize that embracing both a Key Opinion Leader (KOL) strategy and an Evidenced-Based Medicine (EDM) strategy will increase adoption of an innovative medical device in the USA.

METHODS

A qualitative study was designed in order to gain first-hand insight into these particular strategies. This study recruited participants who are employees of a medical device company that has developed an innovative Class II or Class III medical device.

Participants were selected based on their role within the company. The participants were involved in developing or executing the marketing strategies. Once pre-screened, these individuals were interviewed one-on-one over the phone. The participants were asked a series of 40 open-ended questions (See Appendix A). Patton's "Qualitative research and evaluation methods" was used as a guide in developing the methods.⁴³ The interviews

lasted approximately 45 – 60 minutes. The data were anonymized and analyzed. In order to measure the success of the marketing strategies, participants were asked about levels of customer adoption and market penetration. Adoption was measured based on number of devices deployed and sales.

RESULTS

A total of nine (9) individuals were interviewed. Each interview was approximately 45 minutes and resulted in roughly a $\frac{3}{4}$ page of bullet-pointed notes using shorthand writing or typed notes. The average word count per interview was 250. Each individual interviewed employed either an evidence-based medicine strategy or a key opinion-leader strategy (or both). These strategies served as pillars of their marketing strategy. However, these strategies were not the only ones being executed. The individuals interviewed were either the CEO or a person on the company's marketing team. All individuals interviewed were privately owned and employed less than 75 people.

Table 1 (below) describes the interviewees. Particular categories were selected for the following reasons:

- **Sub industry:** Medical devices are a broad category that includes 16 sub-categories. By further categorizing these companies, it will be easier to draw conclusions and relationships.

- **Stage:** The company's stage of development (i.e., early, mid, late) is an important category as it is indicative of the time they have spent executing their business plan.
- **Person Interviewed:** In conducting the interviews, there were people in various capacities within the company (i.e., CEO, marketing specialist, director of marketing, etc.). This could potentially affect their responses as they would have a different perspective of the company's state.
- **Sales:** Once there are sales, it can be assumed that there is some degree of customer buy-in and therefore some degree of success.
- **Number (#) of KOLs:** This category is part of my hypothesis to be assessed.
- **EBM Strategy:** This category is part of my hypothesis to be assessed.

Table 1: Summary of Respondents and their Respective Companies

ID	Sub Industry	Stage	Person Interviewed	Sales	# of KOLs	EBM Strategy
1	Neurology	Early	CEO	No	2	Yes
2	Dental	Early	CEO	Yes	12	Yes
3	Dental	Mid	Marketing	Yes	7	Yes
4	Dental	Mid	CEO	Yes	12	Yes
5	Orthopedics	Mid	CEO	Yes	25	Yes
6	Hematology	Early	CEO	Yes	4	No
7	Optometry	Early	CEO	No	3	Yes
8	Surgical	Early	Marketing	No	5	Yes
9	Hematology	Late	CEO	Yes	8	No

ANALYSIS/DISCUSSION

The transcripts of the interviews were reviewed carefully and similarities in responses were noted and tallied. The answers to specific questions were tallied and arranged in tables that can be found below. Once the interviews were complete, a comparison

allowed key findings (i.e., recurring themes) to be identified. Following the identification of key findings, relevant quotes were extracted and mentioned in the discussion. In analyzing the qualitative information collected during the interviews, the following key findings were identified:

Benefits of a KOL Strategy

There are many benefits that stem from employing a KOL marketing strategy. Aside from “increasing adoption”, the interviews revealed several other important benefits that arose from a KOL strategy; as listed in Table 2.

Table 2: Benefits of a KOL Strategy

ID	Benefit	Avg. # of KOLs	% of Companies with Sales
ALL	Convinces peers and colleagues to adopt	9	67%
ALL	Disseminates scientific information in an “easy to swallow” format (i.e., medical education)	9	67%
ALL	Tests the product during development	9	67%
ALL	Provides exposure/publicity	9	67%
ALL	Builds credibility and validates product	9	67%
1, 2, 4, 5, 6, 9	Identifies new opportunities and indications for use	11	83%
1, 2, 3, 8, 9	Provides feedback to help guide product development	7	60%
1, 2, 3, 5, 8	Guides clinical research	10	60%

1, 5, 7	Guides regulatory compliance	10	33%
1, 5, 8	Helps guide product purchases	11	33%
1, 2	Helps with competitive analysis and comparison	7	50%
7	Guides company's bioethics	3	No
1	Supports patient advocacy	2	No

From these results, it is evident that all respondents agreed on the importance of a KOL strategy. As Respondent 5 remarked: “KOLs are the best marketing strategy a medical device company can have. An evidence-only strategy would simply not work”.

Respondent 6 concurred: “KOLs are the most powerful tool of all”. It should also be noted that of the six companies that used KOLs to identify new opportunities and indications for use 83% had sales. Perhaps this strategy should be prioritized.

Drawbacks of a KOL Strategy

KOL strategies are extremely beneficial; however, there are certainly drawbacks to this approach that were discussed during the interviews. In order to gain credibility and scientific validation, companies often partner with academia. This results in KOLs becoming early users but not early customers. While the KOLs were always interested in running clinical studies and publishing results, their visibility often makes them conservative. Academics often delay real adoption (i.e., purchasing the product) until the new technologies are well proven. Publications, clinical trial leadership, and scientific advisory board membership therefore do not always indicate an early adopter. When

early adopters tell you that your solution resolves an important problem, you'll know you're on the right track.

In several companies, KOLs were paid by the company for their services. This often creates a professional bias and the KOL can become less influential, damaging the overall marketing strategy. In discussing this strategy with one company, they would pay their KOLs \$5,000 for a single event, in addition to all of their travel expenses. Oppositely, another company recruited KOLs who were genuinely interested in their product for research purposes. In this scenario, the KOL bought the product at full price and championed it for free. Unfortunately, conflicts of interest will arise when clinicians become marketing and PR “mouthpieces” for new medical devices.

Interestingly, as summarized in Table 3 (below), this comparison of paid versus unpaid KOLs suggests that sales were achieved 100% of the time if the KOL is paid. In the companies that did not pay the KOLs, sales were only achieved 50% of time. I conclude that paying KOLs may increase the likelihood of achieving sales.

Table 3: Relationship Between Paid versus Unpaid KOLs

ID	Paid KOLs	Avg. # of KOLs	Sales	EBM
2, 3, 5	Yes	15	100%	100%
1, 4, 6 – 9	No	6	50%	67%

Identifying and recruiting KOLs

Table 4 (below) lists the methods used by the respondents to identify and recruit KOLs.

Asking for references from clinical collaborators and networking at conferences and exhibitions were two methods used by all of the respondents. In looking at the percentage of companies with sales, these methods seem to be the most successful. The six methods mentioned by the respondents are outlined below:

Table 4: KOL Recruitment

ID	Recruiting Method	Avg. # of KOLs	Sales
ALL	Asking clinical collaborators for recommendations	9	67%
ALL	Networking at conferences and exhibitions	9	67%
1, 2, 4, 5, 7	Networking with industry colleagues (device industry execs, VC's, consultants) who have previously sold to this customer segment	11	60%
1, 2, 4, 5, 7, 8	Reading the literature that has been produced and looking at the literature being produced in segment. Tracking down the researchers and clinicians that are doing work in your area and recruit them.	10	50%
2, 3, 8	Identifying competitive or non-competitive products in the same segment, and seeking out the early buyers and their KOLs	8	66%
1, 5	Approaching candidates on scientific advisory boards of previous or other existing startups in segment	13	50%

Types of KOLs

The interviews revealed that there are different types of KOLs. In a strong KOL portfolio, there will be many different types of KOLs that will satisfy the many different roles. KOLs differ on several indices, which I will outline:

- Degree of influence: Some KOLs are more influential and powerful than others. Well respected, and most recognized KOLs tended to be older and very well versed in the particular segment. As Respondent 2 said, “Mr. XXXX is the Dental God. He has been around forever, and everyone listens to him”. Respondents 1, 2, and 5 allowed me to conclude that each KOL has a different reputation in the industry based on their contribution and their general level of activity. Getting the “top dog” in the industry is the goal. This individual is typically 60+ years old.
- Type of influence: KOLs varied in who they had influence on, whether it be peers/colleagues, consumers/patients, and hospital administrators.
- Role in the company: Depending on their agreement, KOLs served various roles. Some KOLs were extremely active in clinical research and product development, while others were merely spokespeople for the company and product. As Respondent 2 said, “We have some guys good at public speaking, while others are better one-on-one.” In order to manage this, the company developed a KOL spreadsheet that outlines/details each KOL and their specific roles, their strengths and their weaknesses.

KOLs are often first customers, but not always

In almost all discussions, the KOLs recruited by the company became the company’s first buyer. As shown in Table 5, the situation varied, with the customer being either focused on research/academia or a practicing clinician with little ties to research. In some cases, however, the KOL was given the product at no cost. This occurred when the KOL was a researcher. Given tight budgetary restraints in academia, and the fact that researchers can help companies with their clinical research, it is no surprise that these KOLs were given product at no cost.

Table 5: KOL Buying Behaviour

ID	Purchased VS. Given	Researcher or Practicing Clinician	Sales
2, 3, 4, 5, 6	KOL purchased product	Practicing clinician	100%
2, 3	KOL was given product	Researcher	100%

FDA vs. EBM

The Food and Drug Administration (FDA) is a federal agency in the United States that acts as the governing body for many different things, including medical devices. In the medical device industry, regulatory approval is necessary in order for the product to be legally sold. All companies interviewed had dealt with the FDA in some capacity, as the medical devices being developed required some level of approval. It was the general consensus that the FDA merely ensures the product is safe and the risks associated with use are mitigated – that is it. The bar is very low in terms of clinical validation, clinical efficacy and clinical effectiveness. EBM goes above and beyond evidence required by regulatory bodies. However, in speaking with numerous individuals from a variety of industries, it was noted in one conversation that EBM was not necessary as the

requirements put forth by the FDA were sufficient enough to produce sales. This conversation also revealed that the FDA had recently increased the evidence required for approval. With that said, each company’s EBM strategy was unique in strength and depth. It should be noted that the degree of evidence required depends on specialty and product.

Table 6: FDA vs. EBM

ID	FDA vs. EBM	Sales
1, 2, 3, 6, 9	FDA approval is sufficient evidence for customer buy-in	60%
5, 7, 8	EBM is required for customer buy-in	33%

Interestingly, as outlined in Table 6, only two companies did not employ an EBM strategy (ID 6 and 9); however respondents 1, 2, and 3 claimed that FDA approval was sufficient for customer buy-in yet they still employed an EBM strategy. Respondents 6 and 9 both achieved sales, while Respondent 1 did not, despite employing an EBM strategy. This result poses two questions: 1) When is an EBM strategy necessary? and 2) Under what conditions is it sufficient to obtain only FDA approval?

EBM is very cumbersome and expensive

Despite the hype and importance that surrounds EBM, it is a very expensive and time-consuming endeavor. Clinical studies can run anywhere from thousands, to millions, with an average cost in the tens of thousands.⁴⁴ An EBM strategy must be carefully planned and executed by trained and experience professionals. KOLs play a very important role in guiding this strategy, as they are the clinicians on the ground level. Table 7 (below) suggests that just one clinical study can cost tens of thousands, even

hundreds of thousands. No data was collected from Respondents 3 and 4 regarding this topic.

Table 7: FDA vs. EBM

ID	Cost of One Clinical Study
1, 2	Upwards of \$75,000 - \$100,000
5, 7, 8	\$100,000+

EBM and KOL strategies can leverage other strategies

With a KOL and EBM strategy being implemented, the companies interviewed also enjoyed the benefits of leveraging another strategy, namely a reimbursement strategy.

This strategy was not listed in the literature review that I completed during my research.

As these medical devices are considered innovations, sometimes there is a not an appropriate billing code associated with the device or the procedure involved. Although there are usually predicate devices, and pre-existing billing codes that can be used, having a specific billing code is much more desirable. If there is no billing code, the doctor cannot charge the patient and therefore the device will not be sold. Subsequently, a solid reimbursement strategy is necessary to ensure that the user can get a sufficient ROI.

Respondent 5 indicated that their KOLs were able to help create novel billing codes for their device. Their ability to do so was fuelled by clinical evidence that was produced from the EBM strategy. This is significant as the link between reimbursement strategy and marketing strategy did not appear during my review of the literature review.

KOL and EBM: The Chicken or The Egg

An interesting relationship exists between a KOL marketing strategy and an EBM strategy in that historically EBM was in-part developed to supplement a KOL strategy. EBM goes above and beyond most required evidence set forth by the FDA. An EBM strategy advocates that purchasing decisions, of medical devices for example, should be based on scientific evidence as opposed to the perceptions of doctors and potentially biased views of KOLs. In order to recruit and retain KOLs, it is important for the company to have strong clinical evidence. However, KOLs play a defining role in developing the EBM strategy. There is clearly a level of evidence beyond FDA approval that is required of medical device companies in order to attract suitable KOLs. Table 8 (below) summarizes the responses regarding this question. As Respondent 5 said, “As long as there is some scientific proof, not even necessarily FDA approval, KOLs are able to see the bigger picture, the science, and they will be your champions”.

Table 8: What Comes First: KOL strategy or EBM strategy?

ID	Comments
1, 2	KOLs come first, using minimal evidence to support the idea
5, 7	Extensive evidence must be established before attracting KOLs

Niche VS. Mainstream Products

Products can be classified based on their market size and potential for ubiquity. A niche product is made and marketed for use in a small and specialized but profitable market, while a mainstream product has a larger market size and is adopted more broadly. There were distinct differences in responses between companies that sold niche products versus

companies that developed mainstream products. Of the companies that developed niche products, the following similarities were revealed:

Table 9: Characteristics of Companies with Niche Products

ID	Comments
5, 6, 8, 9	KOLs were not paid. This could be because the researcher was genuinely interested in the product and was intrigued by its applications
5, 6, 8, 9	“Sales” wasn’t the only main indicator of success. For example, one respondent indicated the “customer service” was a primary indicator of success.
5, 6, 8, 9	FDA approval was difficult, but it was generally enough evidence for customer buy-in.
5, 6, 8, 9	Advertising budget is virtually non-existent.

In comparing companies with niche products vs. mainstream products in Table 10 (below), companies with niche products were more likely to:

- Have sales (i.e., be successful)
- Have a higher number of KOLs
- Not pay KOLs
- Not employ an EBM strategy

Table 10: Comparison of Companies with Niche Products vs. Mainstream Products

Respondents	Niche	Sales	Avg. # of KOLs	Paid KOLs	Employs EBM
5, 6, 8, 9	Yes	75%	11	50%	50%
1 – 4, 7	No	60%	7	40%	100%

“Sales” as a Key Indicator of Success

During each interview, the question of “how do you measure success?” was posed. In every interview, the first response was always sales. The individuals being interviewed remained tight-lipped regarding specifics, but stated their success was tied tightly to their overall business strategy. Another recurring theme included whether or not the company was cash-flow positive. Although all companies in question were not cash-flow positive, a measure of success and a primary goal was to firstly establish themselves as a company with sales, followed by becoming cash flow positive. Another interesting response to this question by Respondent 9 was “customer service”. This respondent indicated having a quality product and a happy customer was an indicator of success. In fact, this respondent delivered annual surveys to all their customers in order to gauge their level of overall satisfaction. Initially, this was not expected. Originally, market penetration and speed of adoption were thought to be the primary indicators of success. Following the interviews, the data revealed otherwise.

Of the nine companies interviewed, three of the companies did not have sales. That is, they had developed a product but had not achieved sales by selling to customers. This could be due to a number of factors that will be discussed. If sales is an indicator of success, what separates the three companies with no sales, from the 6 companies with sales. I summarized the responses from these two groups in Table 11.

Table 11: Comparison of Companies with Sales vs. Without Sales

Respondents	Sales	Avg. # of KOLs	Paid KOLs	Employs EBM	Niche Product	Early Stage
1, 7, 8	No	3	0%	100%	33%	100%
2 – 6, 9	Yes	11	50%	67%	50%	33%

Based on this comparison, the lack of sales can possibly be attributed to the number of KOLs or the current stage of the company. The latter would seem to make more sense, as early stage companies are in their infancy and require more time to establish themselves in the market. Particularly in the medical device industry, as gaining regulatory approval can take years. It should also be noted that companies that pay their KOLs are more likely to achieve sales. Of the companies that do not have sales, they also do not pay their KOLs. It is interesting to note that of the companies with sales, only 67% of them employ an EBM strategy.

CONCLUSION

This study assessed whether embracing both a Key Opinion Leader (KOL) strategy and an Evidenced-Based Medicine (EDM) strategy will increase adoption of an innovative medical device in the USA. Based on the literature review and the results of this study, key opinion leaders and evidence-based medicine are critical components of medical device marketing strategies. The KOL strategy stood out as highly important in both the literature and the study, while the EBM strategy was not always necessary. It is clear that engaging KOLs is necessary to build credibility and influence peers. The interviews revealed that there were many different benefits associated with adopting a KOL strategy, not just increased product adoption. The most common benefits included bench-testing, exposure, publicity, building credibility and disseminating scientific information. However, these benefits come at a cost, as it was revealed that paying KOLs may have a positive impact on success. Conveniently, there are also various ways in which KOLs can be identified, with networking and requesting references being the most common.

Consistent with real-life experience, the results suggested that academic KOLs are unlikely to purchase the technology, while practicing clinicians will be the first customers.

With regards to EBM strategies, clinical evidence to support both economic viability and patient welfare is essential to medical device innovation. Most of the people interviewed argued that a KOL strategy is more important and more powerful than an EBM strategy. However, in order to attract and retain KOLs, it is important to have strong, empirical evidence to support claims. Conveniently, these clinical claims may be achieved through FDA certification. When compared to the FDA, an EBM strategy is much more robust and requires proof of not only safety, but also economical effectiveness and efficacy. The FDA merely ensures safety, while an EBM approach takes into account cost effectiveness and clinical outcomes (i.e., better, faster, stronger cheaper). As noted in the results, an EBM strategy can be very costly and therefore some companies may not be able to afford or justify spending thousands of dollars on clinical studies. Depending on the product, FDA approval may be all the support and evidence a company needs to gain achieve sales.

The hypothesis that a strong KOL strategy and a strong EBM strategy is critical for success finds qualified support. Interestingly, one respondent was able to leverage a reimbursement using a KOL and EBM strategy. Additionally, the results suggested that companies with niche products may have an advantage in terms of sales and the need to employ an EBM strategy. Measurements of success varied between companies; however, measuring sales was a commonality between all companies interviewed. While each

strategy on their own has holes, a combination of both a KOL strategy and an EBM strategy may increase the likelihood of sales in the medical device industry. The data presented in this paper uses a small sample size ($n = 9$) and therefore I recommend that in order to make concrete claims, further research must be carried out. Further research regarding marketing in the life sciences industry as a whole is necessary because of the industry's particular nuances and issues that are often overlooked by general marketing scholars.⁴⁵

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APPENDIX A

MRP – Victoria Smith List of Questions

Qualifying

- What is your position in the company?
- Who is responsible for the development and execution of the marketing plan?
- When was/will be product launch?
- Describe your product
- Who is your customer?

General

- Tell me about the marketing strategies your company uses to increase product adoption
- How successful do you think these strategies have been?
- Describe your company's indicators of success?

Key Opinion Leader (KOL) Questions

- What is your opinion regarding KOL strategies?
- What has been your experience with engaging KOLs in the medical device industry?
- What has your company done to engage KOLs?
- What benefits have resulted from engaging KOLs?
- At what point in the product life cycle have you engaged KOLs?
- What do you think is the best method for identifying KOLs?
- What are some of the indicators of a suitable KOL?
- How many KOLs have you targeted?
- How many are on board?

Evidenced-Based Medicine (EBM) Questions

- How do you define the "clinical questions" your product studies must answer?
- How does the relationship between the scientific team and the marketing team affect clinical studies?
- The FDA requires a certain level of evidence. How do you feel this level compares to the level your potential customer requires?
- Following FDA approval, how many more (if any) clinical studies were conducted or plan to be conducted?
- Describe the amount of evidence (in terms of clinical studies, case studies, etc.) that has been collected
- What type of empirical evidence do you collect (randomized, triple-blind, placebo, etc)?
- Which type of evidence do you feel is most compelling and why?
- What are the reactions of your potential customers when they are presented with your clinical evidence?

Measurable Results

- How do you measure the effectiveness of your company's marketing strategies?
- How do you measure speed of adoption?
- How do you measure market penetration?
- What other measures do you use?
- What are your yearly sales? (Get multiple figures).
- How many devices do you have deployed? In how many facilities?
- What is your total addressable market?

Ending

- That covers the items I wanted to discuss with you. Is there anything else you would like to add?
- Is there anything you think I should have asked you, but didn't?