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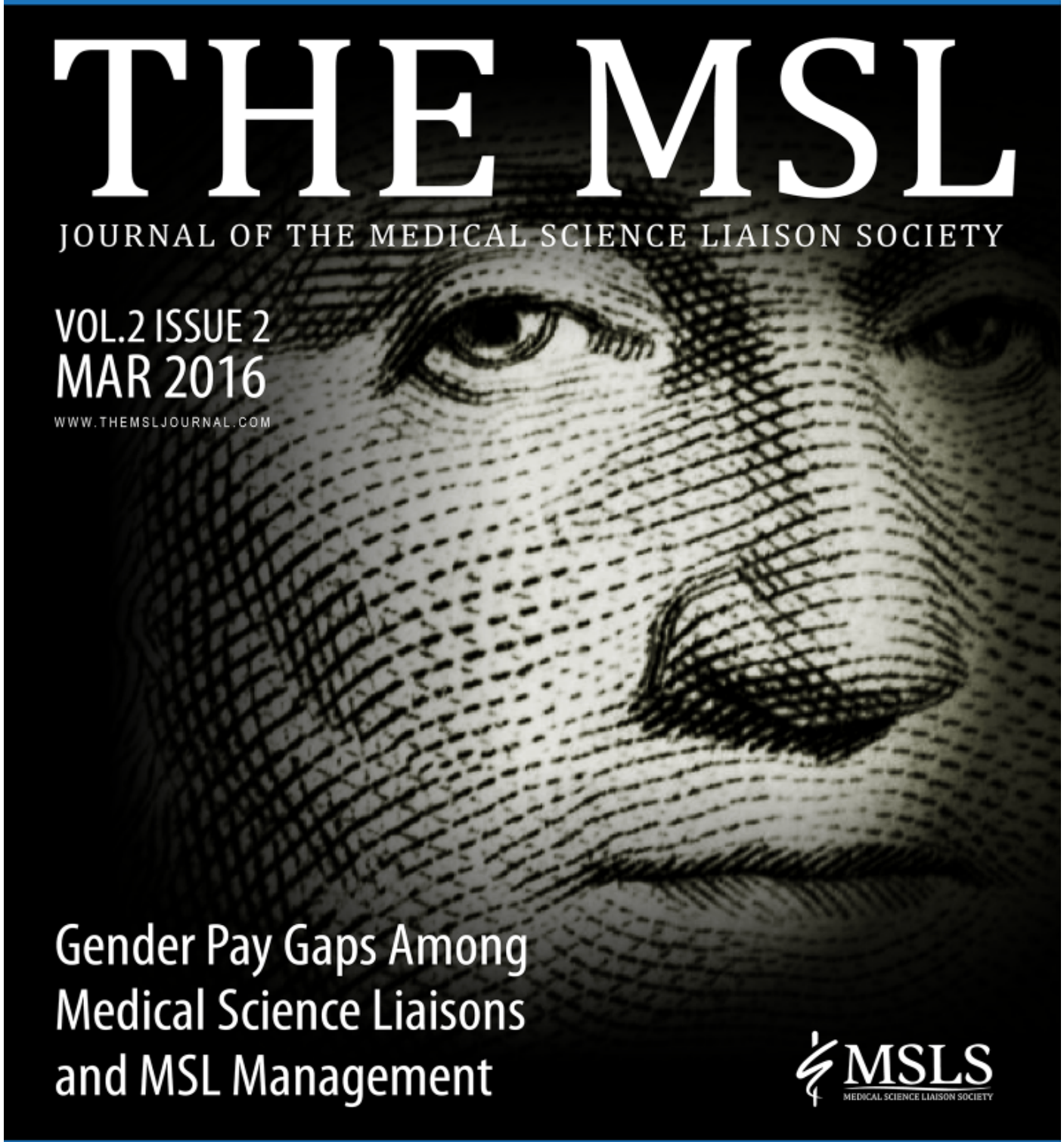

Gender Pay Gaps Among Medical Science Liaisons and MSL Management

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Study Reveals U.S. Salary levels For New And Experienced MSLs As Well As MSL Management

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Study reveals average salary and starting salary levels for both Medical Science Liaisons and MSL management in the U.S.

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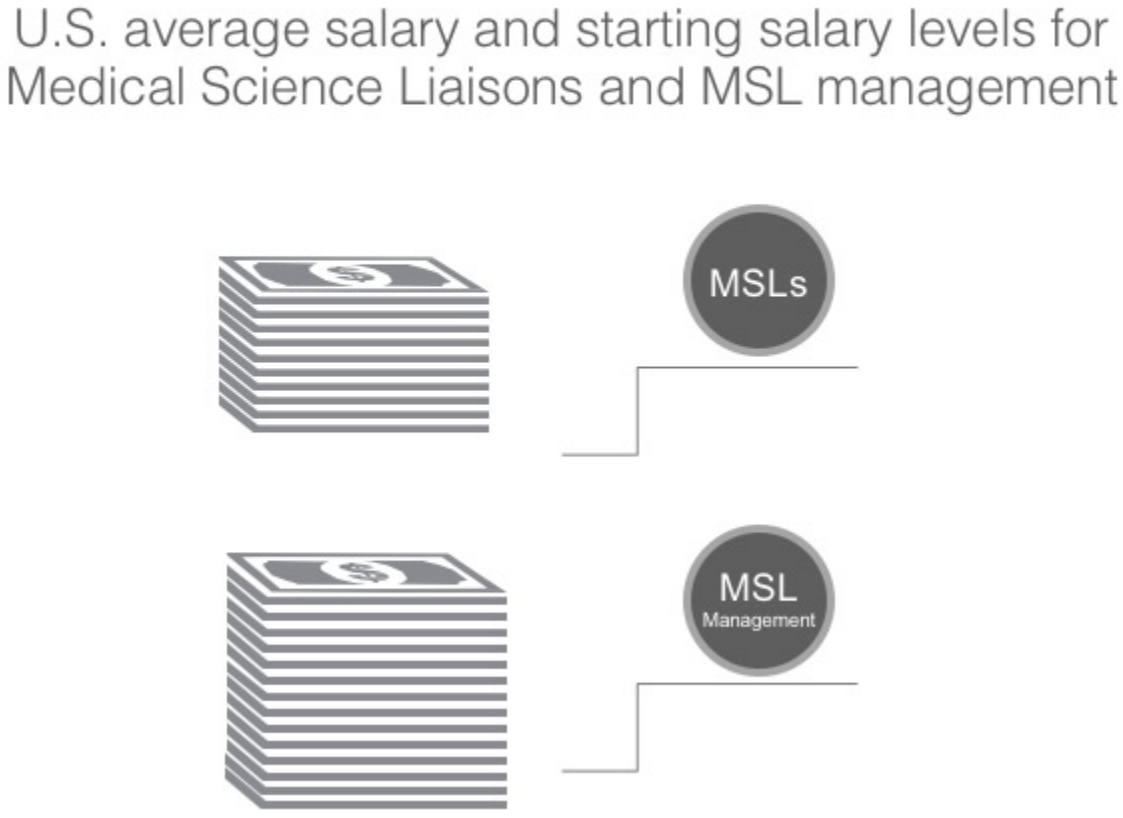

Title:

Study reveals average salary and starting salary levels for both Medical Science Liaisons and MSL management in the U.S.

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The author declares no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Key Words

Medical Science Liaison, Compensation, Medical Science Liaison Salary

Introduction

The Medical Science Liaison Society recently conducted the 2nd annual global survey on Salary and Compensation levels for both Medical Science Liaisons (MSLs) and MSL Management. The 2014 survey was the industry's first global survey conducted on MSL salary and compensation. The primary purpose of the 2015 survey was to gain insights into current global MSL salary and compensation levels across pharmaceutical, biotechnology, medical devices, and other healthcare companies.

Salary and compensation is clearly one of the most important factors in successfully recruiting and retaining the best MSL talent. It's crucial for companies to ensure the compensation they offer is competitive by benchmarking against others in their industry and region. However, prior to the global MSL Salary & Compensation Survey conducted by the MSL Society, there has never been a reliable nor robust source for MSL salary and compensation levels.

The 2015 survey includes 1,259 MSL professionals from 69 countries, and is the largest database of MSL salaries in the world. As a result, it is the most comprehensive and reliable resource on both U.S. and global MSL salary and compensation levels.

However, what follows is a subset of the full report which includes only U.S. data focusing on various specific salary calculations for both MSLs and MSL leadership never revealed previously.

Methods

The 2015 MSL Salary & Compensation survey includes 1,259 MSL professionals from 69 countries. The original report and data was made available in multiple versions including the overall global results and 9 individual countries: Australia, Brazil, Canada, France, Germany, Italy, Spain, U.K., and USA.

The online survey was open from November 9th to December 31st, 2015 using Survey Gizmo survey software. Both fully completed and partial surveys were counted in the results. The survey was only open to current MSLs (or equivalent title) and MSL management. Respondents were only allowed to participate one time and duplicate surveys from a single email address were not accepted. The survey results were not weighted.

Respondents were invited to participate in the survey through a range of sources including:

- Announcements in the "Medical Science Liaison & Medical Affairs Networkers" LinkedIn group as well as other LinkedIn groups
- The MSL Society electronic newsletter

- Personal direct LinkedIn contacts of the author

As this was not a probability-based sample, calculating the theoretical margin of sampling error is not applicable. However, as with probability surveys, it is important to keep in mind that results are estimates and typically vary within a narrow range around the actual value that would be calculated by interviewing everyone in a population. Again, as with probability surveys, on occasion the results from a particular question will be completely outside a typical interval of error.

There are many types of survey error that can limit the ability to generalize to a population. Throughout the research process, The MSL Society followed a Total Survey Quality approach designed to minimize error at each stage.

Results

The U.S. data includes 600 MSL professionals consisting of 516 Medical Science Liaisons (MSLs) and 84 MSL Leaders. When split by gender for all participants in the U.S., 51% of the respondents were male, and 49% were female. The U.S. data includes MSL professionals across company types (pharmaceutical, biotechnology, clinical research organizations (CRO), diagnostic, and medical device) and various formal educational levels representing a wide range of years of experience. The salary calculations in each figure are for base salaries only and do not include bonuses and other compensation.

The first question of the survey asked if the participant was currently an MSL or MSL management. (See Figure 1) Only those who responded as being currently in one of these two roles were allowed to continue with the survey. In the survey, the majority of respondents from the U.S. reported being an MSL.

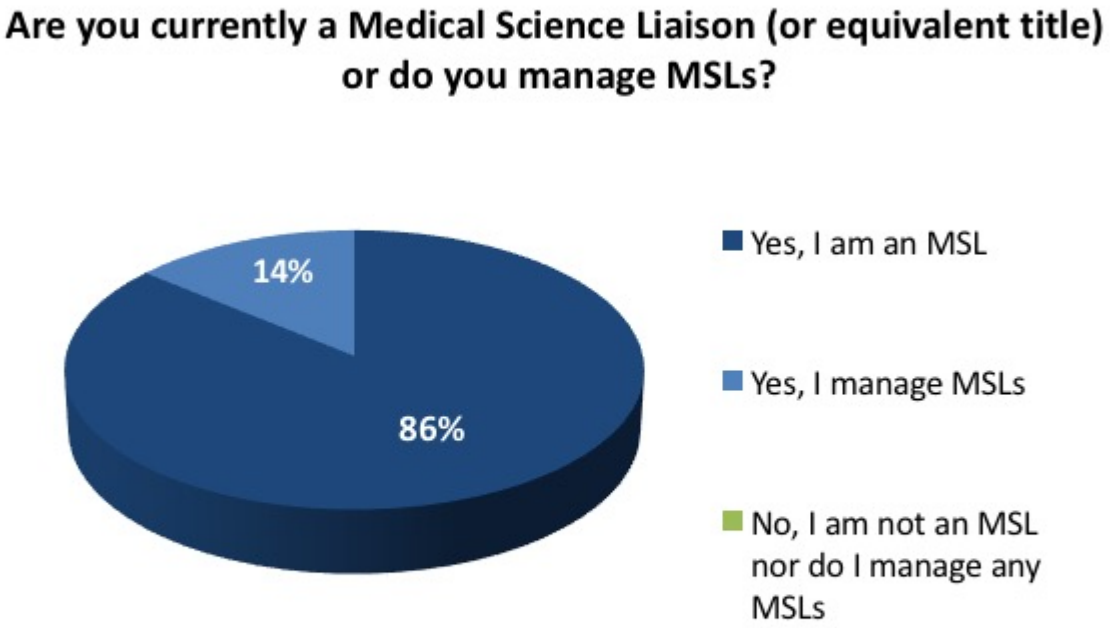


Figure 1

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

As expected there is a difference in salary levels between MSLs and those in MSL management. The average was calculated based on whether a respondent identified themselves as an MSL or MSL manager. (See Figure 2). Salaries for an MSL manager are considerably higher than those for an MSL. In our study MSL managers are are paid 33% more than MSLs.

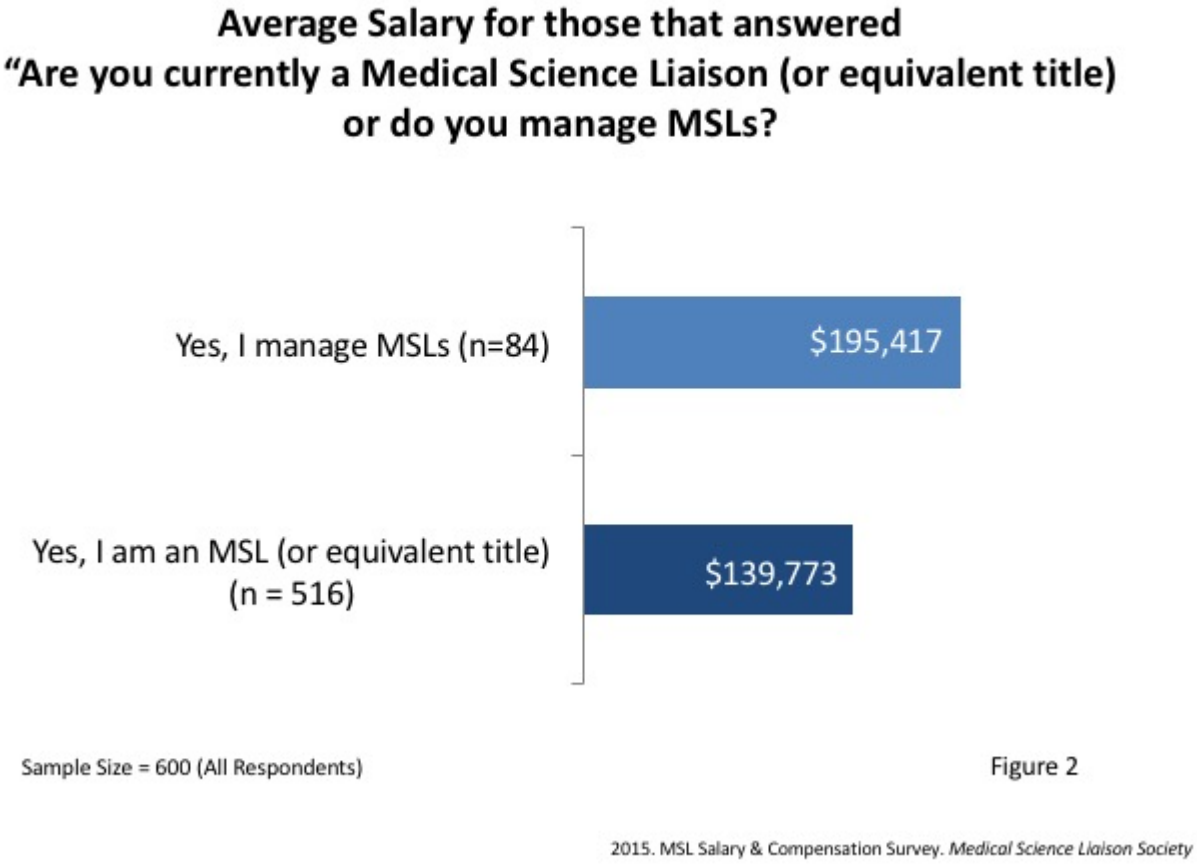
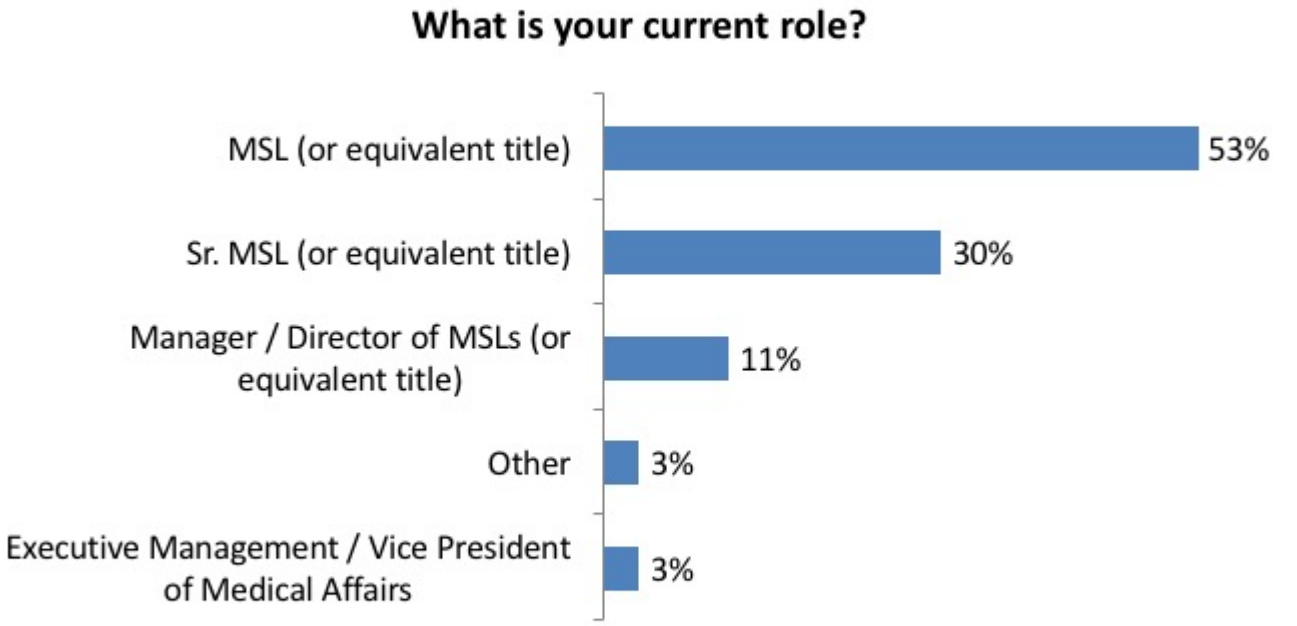


Figure 2

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

The survey then asked participants to specify their role based on a number of choices. (See Figure 3) The majority of participants were either MSLs or Sr. MSLs. Interestingly, some that identified themselves as an MSL in the first question, chose "Manager/Director of MSLs" for this question presumably because they are performing dual roles as an MSL while simultaneously managing a team of MSLs.

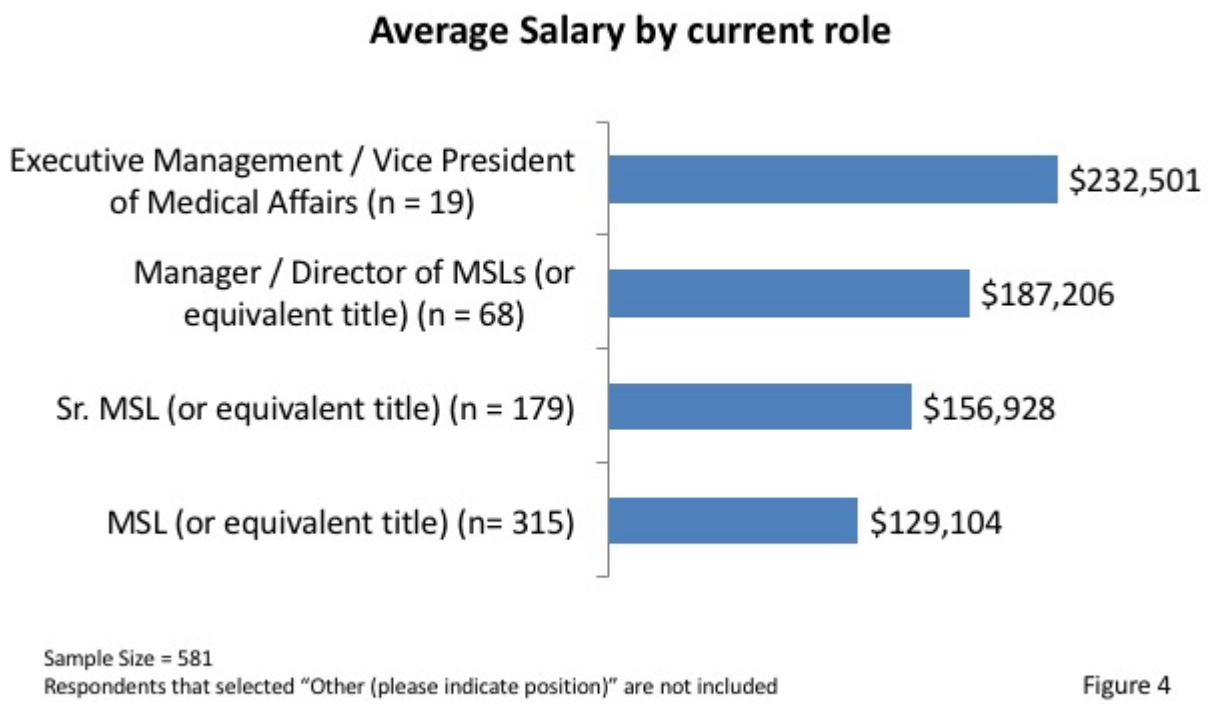


Sample Size = 600 (All Respondents)

Figure 3

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Presumably the greater amount of responsibility in one's role will result in a higher salary. The average salary based on current role was calculated to highlight this. (See Figure 4) There is a clear progression of higher salaries correlated with an increasingly amount of responsibility. For example, on average, a Sr. MSL salary is 21% higher than an MSL.

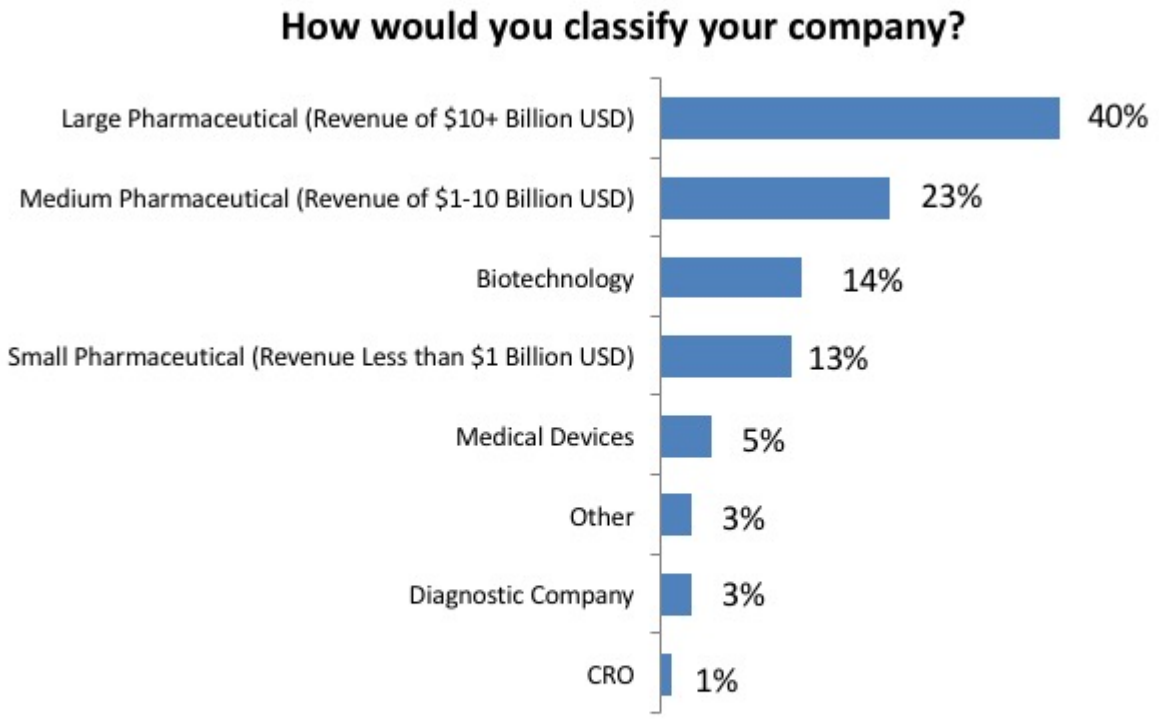


Sample Size = 581
Respondents that selected "Other (please indicate position)" are not included

Figure 4

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

The survey also asked participants to identify their company type. (See Figure 5) Those in the pharmaceutical industry represented 77% of all participants in the survey. Medical Device, CRO, and Diagnostic companies represented a small percentage of participants. However, it is expected that these company types will represent a much larger percentage in future studies due to the growth of the MSL role at these company types.

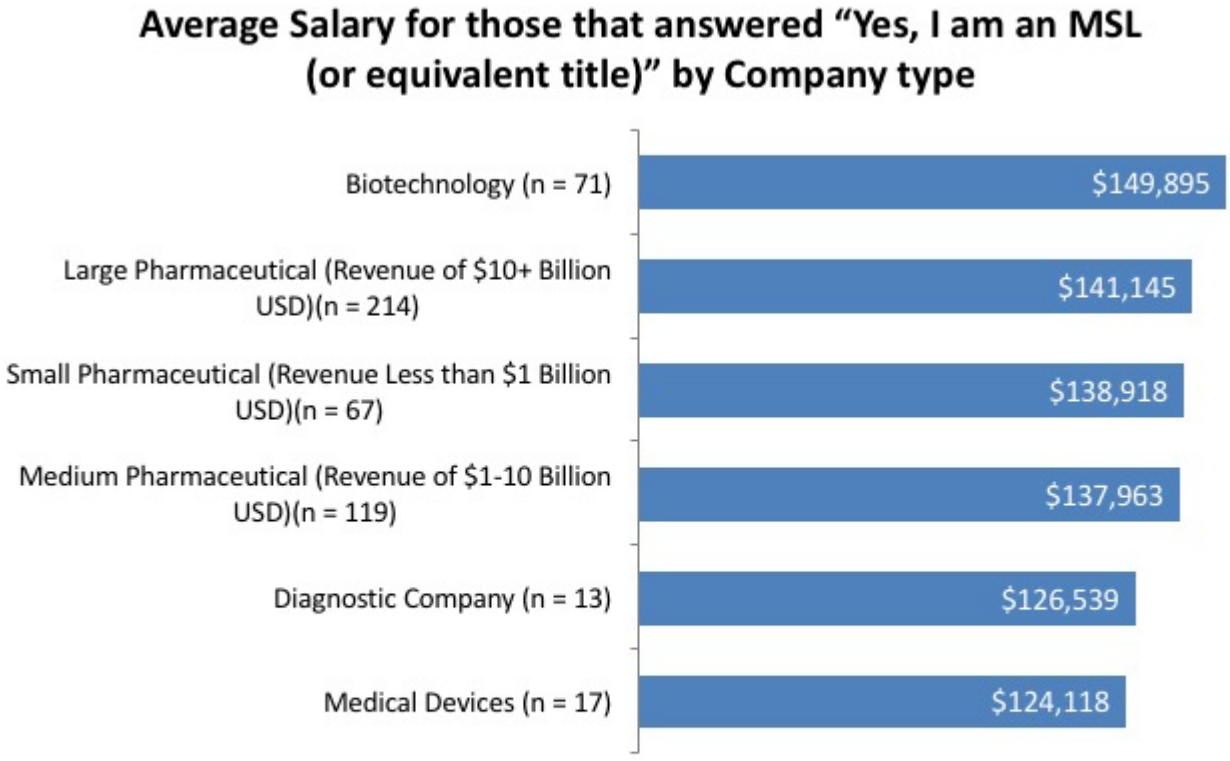


Sample Size = 600 (All Respondents-MSLs and MSL Managers)

Figure 5

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

There are differences in the level of compensation an MSL can expect based on the type of company they work for. (See Figure 6) On average, MSLs can expect the highest salaries when working for either a Biotechnology or Large Pharmaceutical company. For example, when compared to another company type, on average, Biotechnology companies pay 8% more than Medium Pharmaceutical companies.

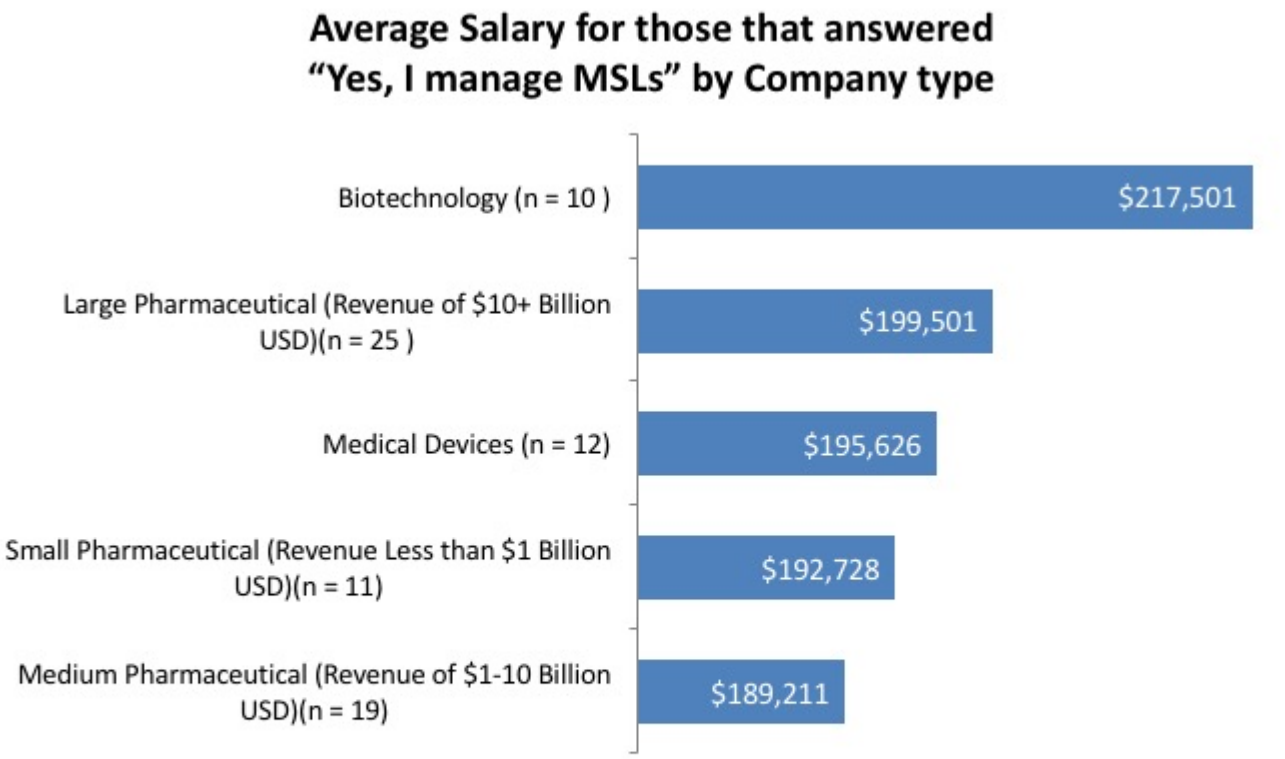


Sample Size = 504
*Respondents that selected "CRO or Other (please specify)" are not included due to low numbers and limited data

Figure 6

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Interestingly for MSL managers, they can also expect, on average, the highest salaries when working for either a Biotechnology or Large Pharmaceutical company as well. (See Figure 7)



Sample Size = 80
*Respondents that selected "CRO, Diagnostic Company, or Other (please specify)" are not included due to low numbers and limited data

Figure 7

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

For example when compared to another company type, on average, Biotechnology companies pay 15% more than Medium Pharmaceutical companies.

The survey also asked participants how many years of MSL and/or MSL management experience they had. (See Figure 8) The majority (62%) of MSLs were relatively new to the role with less than 5 years of experience.

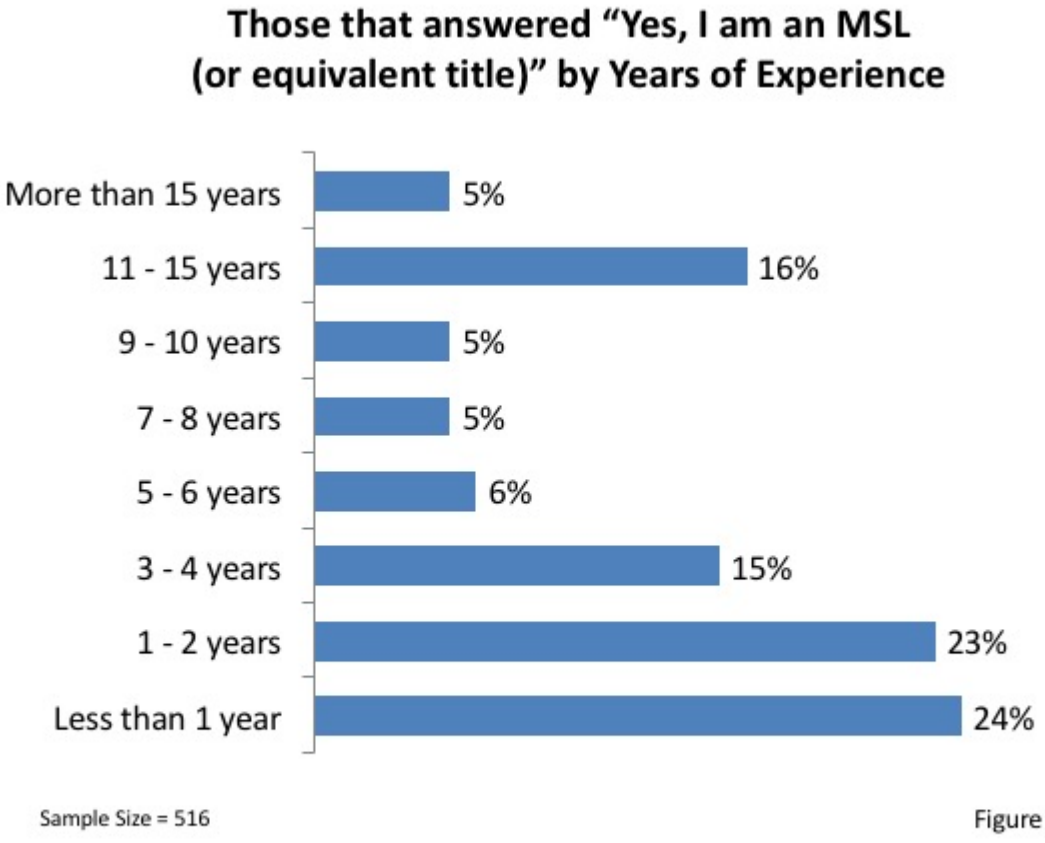


Figure 8

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Generally, an MSL can expect a sizeable salary increase as they gain years of experience. (See Figure 9) On average, an MSL can expect almost a 33% increase in their base salary across a 15+ year career in the role. With 5-6 years of experience, on average an MSL can expect a 27% increase in their base salary. The average starting salary for an MSL across all company types is $123,000.

Figure 9

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

In contrast to MSLs, those that identified themselves as a "Manager / Director of MSLs

(or equivalent title)" were more experienced as a group. (See Figure 10) The majority (52%) of MSL managers had 9+ years of experience.

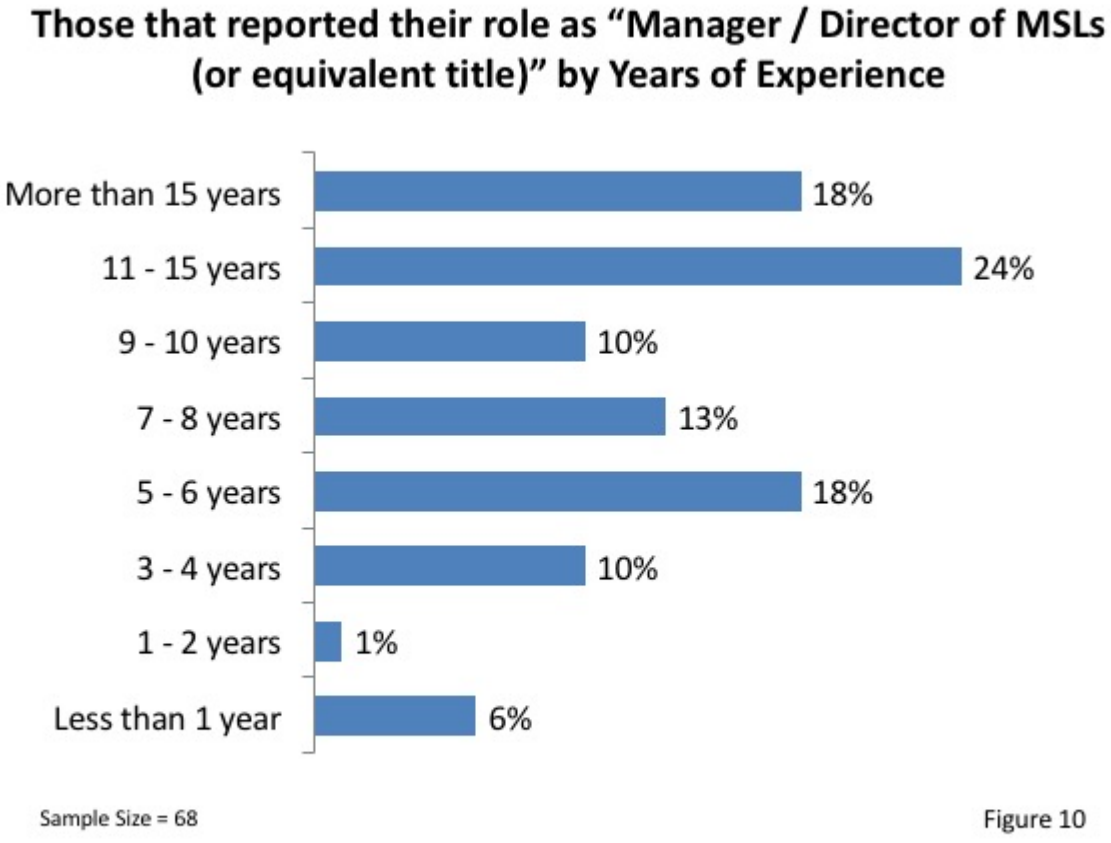


Figure 10

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

As with MSLs, Manager / Director of MSLs can also expect sizable increases in their base salary with experience. (See Figure 11) On average a Manager / Director of MSLs can expect a 25% increase in their base salary across a 15+ year career in the role. With 5-6 years of experience, on average a Manager / Director can expect a 19% increase in their base salary. In this limited sample size, the average starting salary for a Manager / Director across all company types is $162,000.

Figure 11

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Conclusion

Salary and compensation is one of the most important factors in successfully recruiting and retaining the best MSL talent. The results of the MSL Salary and Compensation Survey conducted by the MSL Society provides reliable insights into current MSL salary and compensation levels across pharmaceutical, biotechnology, medical devices, and other healthcare companies. Compensation for both MSLs and MSL managers are influenced by several factors including specific role, years of experience, and company type. The strongest factor impacting base salaries for MSLs is years of experience. On average an MSL can expect an almost 33% increase in their base salary across a 15+ year career in the role.

The importance of the survey conducted by the MSL Society is evident by the fact that salary information specific to the MSL role from traditional salary sources such as the Society for Human Resources Management or third-party websites such as PayScale.com, Glassdoor.com, or Salary.com are both very limited and unreliable. The use of this new survey data will assist companies and specifically human resources management professionals to reliably determine the most appropriate salary bands for both MSL and MSL management, by taking into consideration specific factors that impact salary such as years of experience, education, and possibly others. Although The Society for Human Resources Management has very limited specific MSL salary data, they do recommend that human resources professionals regularly evaluate available market data such as the 2015 MSL Salary and Compensation report conducted by The Medical Science Liaison Society to determine fair market value for positions.

It's crucial for companies to ensure the compensation they offer is competitive by benchmarking against others in their industry and region. The 2015 survey conducted by the MSL Society is the largest and most robust database of MSL salaries in the world. As a result, it is the most comprehensive and reliable resource on both U.S. and global MSL salary and compensation levels. The information gathered from this survey will allow companies to utilize the information to confidently make important business decisions related to MSL and MSL management salary and compensation levels. Furthermore reliable salary information like this

survey may ultimately help both recruit and retain top MSL talent.

References:

2015 Global Survey of Medical Science Liaison Salary and Compensation, Medical Science Liaison Society, 2015.

Additional Resources

The full Global MSL Salary and Compensation Report and 9 individual country reports, which reveals details of these findings and other insights, is available for free for all members of the MSL Society under the resource section of the society website www.themsls.org.

Gender Pay Gaps Among Medical Science Liaisons and MSL Management

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Conflicts of Interest

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Key Words

msl salary, msl, medical science liaison

Introduction

Given the significance of annual salaries both to the individual as well as to the reputation of the employer, any differences in pay based solely on gender will likely be controversial and should cause concern. In economic terms, “gender gap” defines systematic differences men and women achieve in the labor market. In terms of wages, the term is defined as the difference between men’s and women’s wages. (1) In part due to negative economic consequences of gender inequality on the economic environment and society as a whole (2), gender pay gap has been a topic of discussion since the 1960s (1), with The Equal Pay Act, signed in 1963, and Title VII of the Civil Rights Act, signed in 1964 being the first significant milestones towards gender equality. (3) However, after over 50 years since The Equal Pay Act was signed, gender pay gap continues to dominate discussions about equality in the workplace in many industries across the globe due to the fact that women still receive lower earnings than men in almost all occupations. (4) For example, in 2015, full-time female workers in the U.S. earned 79 cents for every dollar earned by men, representing a 21% pay gap. (5)

Also known as a “gender earnings ratio,” the difference in wages between sexes is exemplified by Equal Pay Day: a day that marks how far into the new year women would need to work for their earnings to match those of men in the previous year. (6) In 2016, Equal Pay Day fell on April 12th. The gender pay gap has not changed significantly since 2000, despite women currently holding 49.3% of all jobs (6) (7). The Institute for Women’s Policy Research recognizes the fact that the gender pay gap has been slowly narrowing over the years, but also notes that it will not close, at the current rate, until 2059. (7) The gender pay gap remains an issue both in the U.S. as well as on a global scale across numerous professions.

To date, gender pay gaps have not been studied or revealed within the Medical Science Liaison profession but have been investigated in numerous professions within healthcare and the pharmaceutical industry, including pharmaceutical and biotech sales representatives (8), healthcare sales (9), and medicine (10). Gender pay gaps for medical sales reps were revealed in a 2015 study conducted in the U.S., where female pharmaceutical sales representatives earned $10,403 or 11.0% less than their male counterparts (11), while female biotech sales representatives earned $11,387 or 9.9% less per year. (12)

Gender pay gaps have also been revealed in medicine. A study of physician researchers in the U.S. showed that the mean annual salary for males was $200,000, while females earned just over $167,000, representing an 18% higher salary for male physician researchers. Even after adjustments for work hours, academic rank, research time, specialty and other relevant factors, female physicians earned less than their male counterparts. (10) A U.S. survey of Anesthesiologists also highlighted the gender pay gap in medicine, and revealed a difference in salary of 30%; in 2012, female anesthesiologists earned about $313,000 on average, while their male counterparts earned about $404,000. (13)

Although gender pay gaps have not been studied specifically within the Medical Science Liaison profession, the Medical Science Liaison Society recently conducted the 2nd annual global survey on Salary and Compensation levels for both Medical Science Liaisons (MSLs) and MSL Management, which included salaries for both groups based on gender. While the primary purpose of this survey was to gain a better insight into the present level of MSL and MSL Management salary and compensation levels across biotechnology, pharmaceutical, medical devices, and other healthcare companies, gender pay gap differences were revealed for the first time.

Despite the existence of significant pay gaps in associated professions and industries, including pharmaceutical sales representatives (11), healthcare sales (9), and medicine (10) (13), MSLs and MSL managers are not affected by the significant gender pay gaps experienced in other professions.

Methods

The 2015 MSL Salary & Compensation Survey includes 1,259 MSL professionals from 69 countries. The original report and data were made available in multiple versions, including the overall global results and results for nine individual countries: Australia, Brazil, Canada, France, Germany, Italy, Spain, U.K., and the U.S.

The online survey was open from November 9th to December 31st, 2015 using Survey Gizmo survey software. Both fully completed and partial surveys were counted in the results. The survey was only open to current MSLs (or equivalent title) and MSL management. Respondents were only allowed to participate one time and duplicate surveys from a single email address were not accepted. During the entire research process, the MSL Society ascribed to a Total Survey Quality methodology that is designed to minimize any errors at each stage.

Respondents were invited to participate in the survey through multiple sources, including:

- Announcements in the "Medical Science Liaison & Medical Affairs Networkers" LinkedIn group as well as other LinkedIn groups
- The MSL Society electronic newsletter
- Personal direct LinkedIn contacts of the author

Because of how the survey was distributed, we are not able to calculate a response rate.

We have – and are aware of – no reliable data on the size or characteristics of the global (or U.S.) MSL population. We were therefore unable to determine whether there was any sampling or response bias, so we did not attempt to weight the results. However, the sample contains a balanced gender mix and considerable diversity across other attributes (experience, etc.), and we have no reason to question its representativeness.

For each of six sample groups – all US MSLs, new US MSLs, US MSL managers, all global MSLs, new global MSLs, and global MSL managers – we used a three-step process to assess gender gaps in MSL salaries. We first calculated average salaries for males and females, and checked to ensure that these averages were not distorted by extreme values. We then calculated the difference between average male and female salaries, in both dollar and percentage terms.

Finally, we performed an independent samples t-test comparing the male and female averages to determine whether the dollar gap was statistically significant (i.e., significantly different from zero). We used a 95% confidence level for this test, but the results would have been the same using a 90% confidence level. It is important to note that gender salary gaps could exist in the population even for groups where the sample gap was not significant; in such cases, the sample gap wasn't large enough and/or based on enough respondents for us to reject the hypothesis that male and female MSL salaries were equal.

Results

The 2015 survey includes 1,259 MSL professionals from 69 countries, and is the largest database of MSL salaries in the world. As a result, it is the most comprehensive and only reliable resource on both U.S. and global MSL and MSL management salary and compensation levels in relation to gender pay differences.

Both the global and U.S. data includes MSL professionals across various company types (pharmaceutical, biotechnology, clinical research organizations (CRO), diagnostic, and medical device) and various formal educational levels, representing a wide range of years of experience. The salary calculations in each figure are for base salaries only and do not include bonuses and other compensation.

The overall results had an almost equal distribution of male-to-female respondents for both MSLs, as well as for those that identified themselves as an MSL or management. When split by gender for all participants (MSLs and management) globally, 52% of the respondents were male, and 48% were female. In the U.S., 51% of all the respondents (MSLs and management) were male, and 49% were female.

For MSLs, the U.S. data includes 497 MSLs; 251 or 50.5% of those were female, and 246 or 49.5% were male. The overall average salary for those that identified themselves as an MSL in the U.S. was $135,608 for females versus $143,090 for males (Figure 1). This represents a statistically significant difference of $7482, or just over a 5% gender pay gap for MSLs in the U.S.

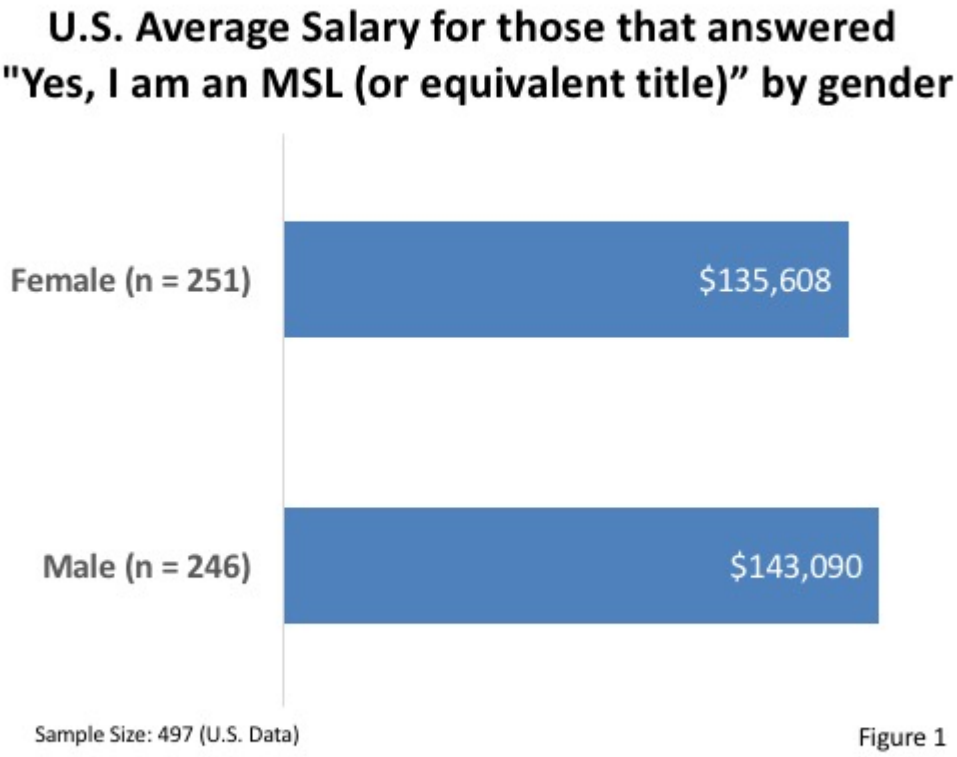


Figure 1

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

The global data includes 1037 MSLs, of which 517 or 49.9% were female, and 520 or 50.1% were male. The gender pay gap difference for MSLs globally was on average lower than in the U.S. The overall average salary for those that identified themselves as an MSL globally was $101,064 for females versus $105,015 for males (Figure 2). This represents a difference of $3951, or just under a 4% gender pay gap for MSLs globally. However, this dollar difference is not statistically significant.

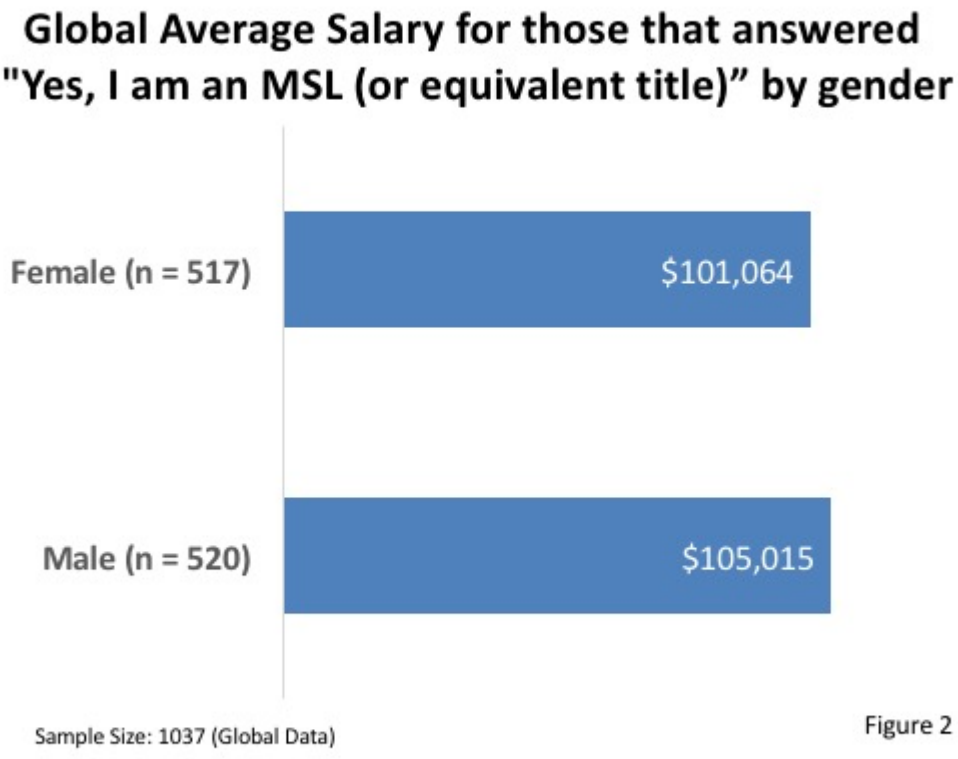


Figure 2

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

For the U.S. data., there was an equal distribution of males and females among the MSLs with less than one year of experience. (Figure 3)

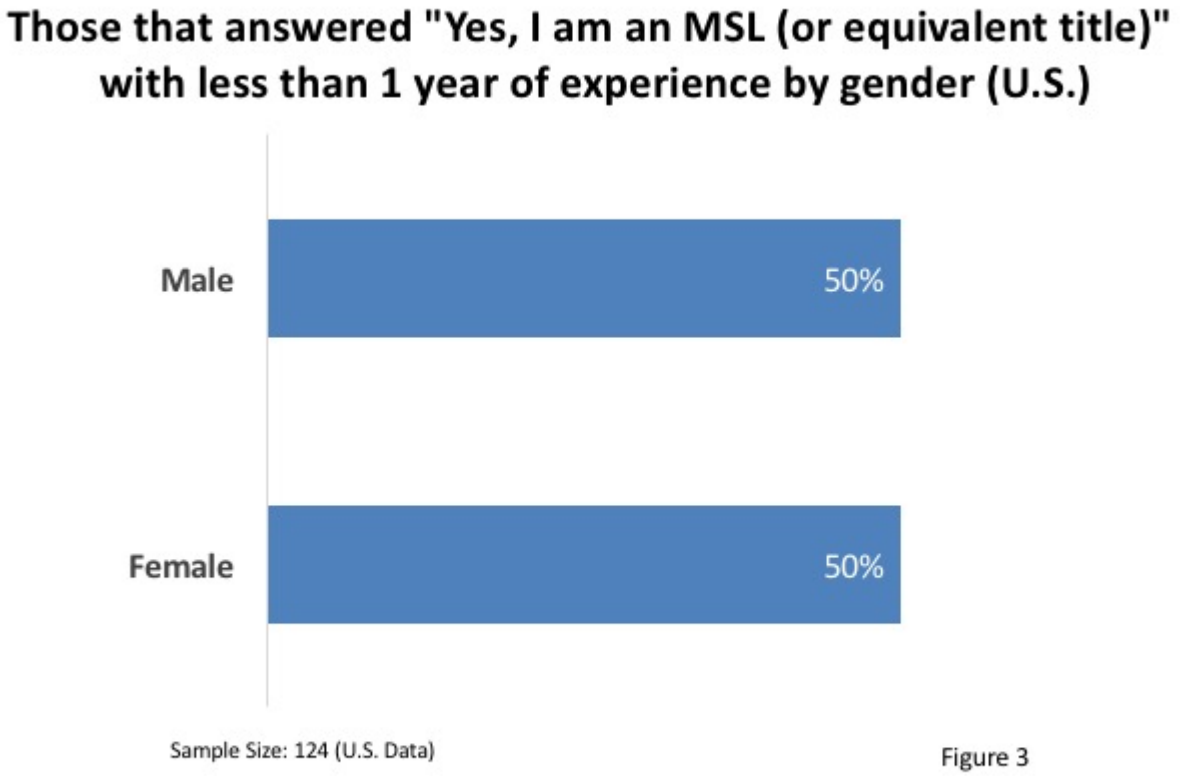


Figure 3

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

For the global data, there was an almost equal male-to-female distribution among the MSLs with less than one year of experience, with 48% male versus 52% female. (Figure 4)

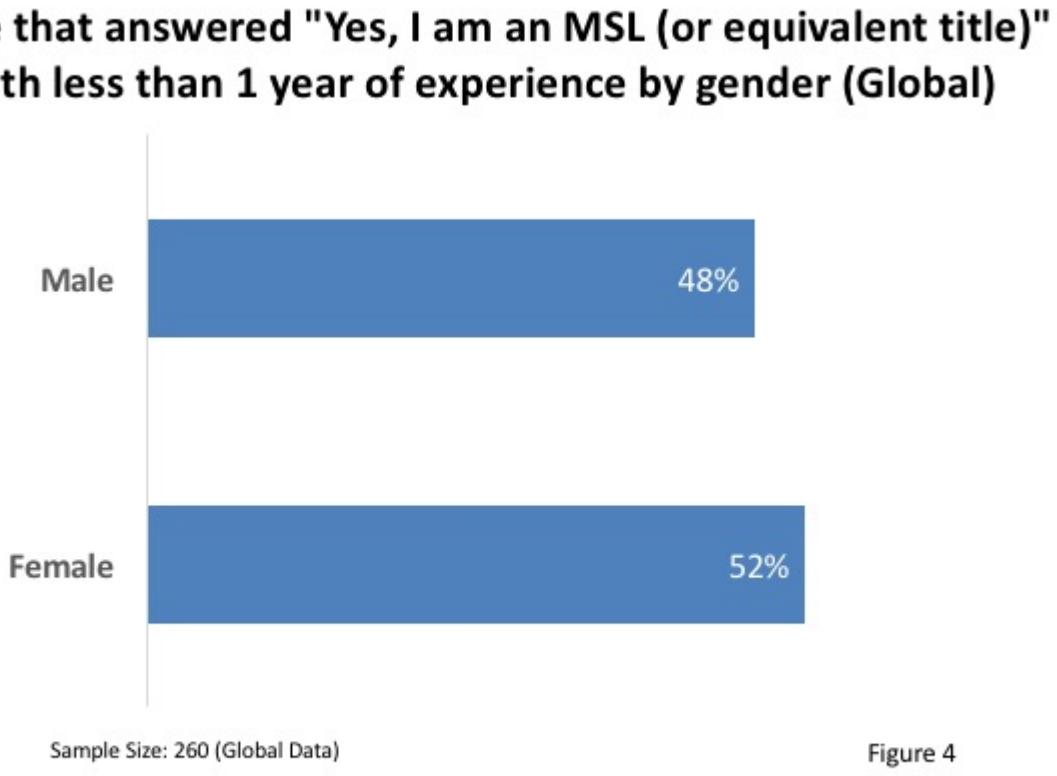
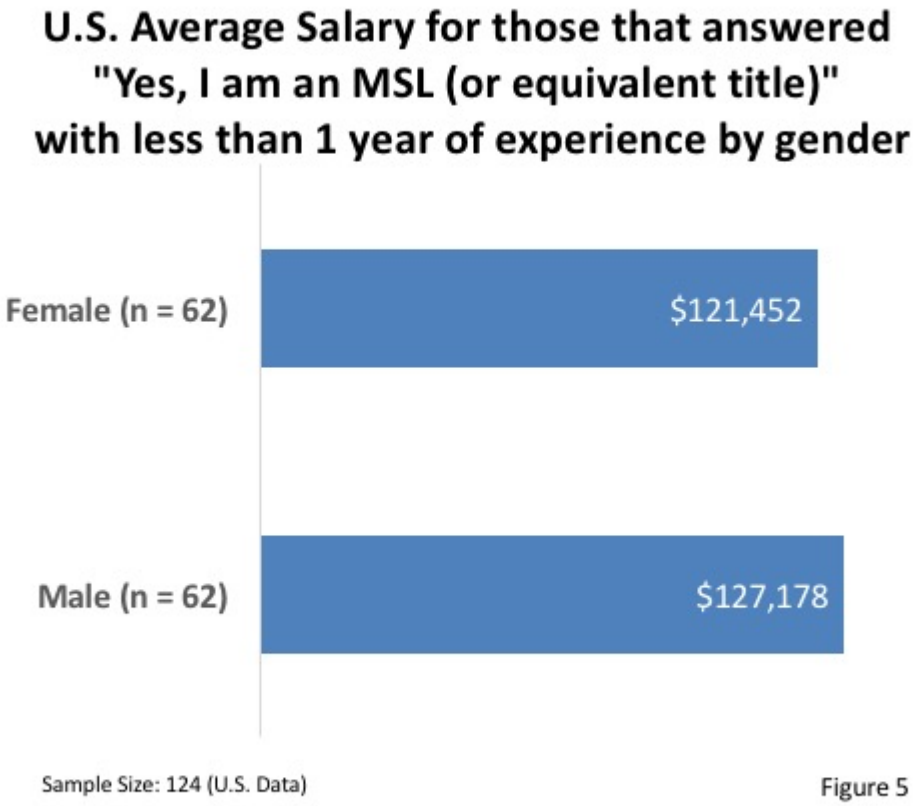


Figure 4

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

For MSLs in the U.S. with less than one year of experience, the gender pay gap was 4.6%, with new male MSLs earning on average $5726 more per year (Figure 5). However, this dollar difference is not statistically significant.

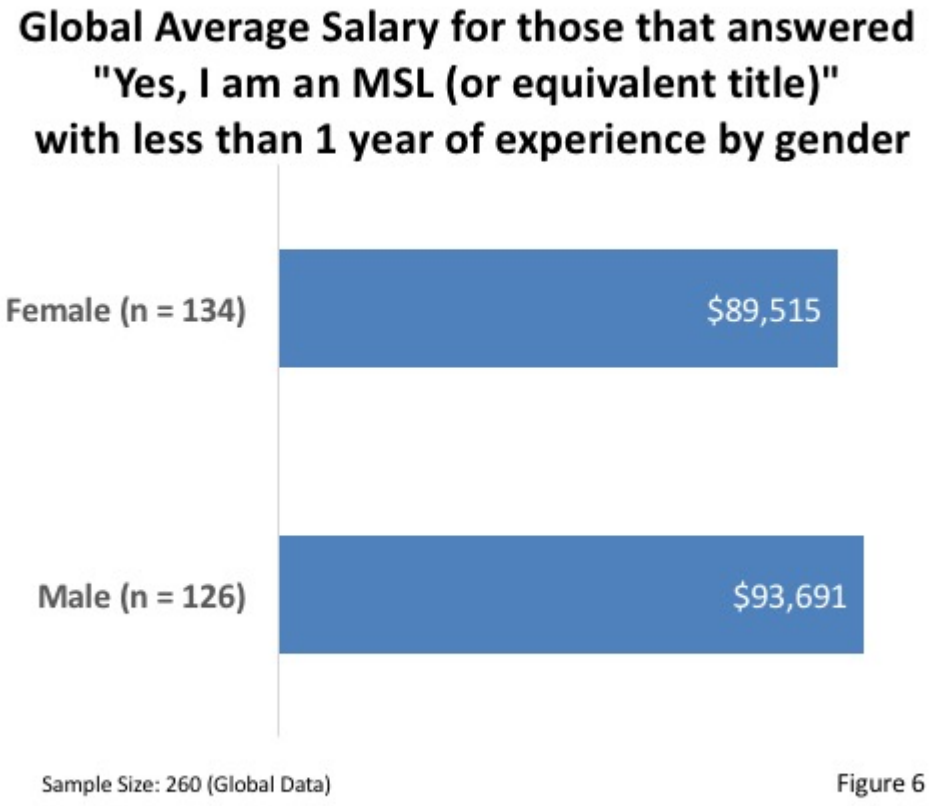


Sample Size: 124 (U.S. Data)

Figure 5

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Globally, for MSLs with less than one year of experience, the gender pay gap was exactly the same as in the U.S. at 4.6%, with new male MSLs earning on average $4176 more per year (Figure 6). As with the U.S. results, this dollar difference is not statistically significant.



Sample Size: 260 (Global Data)

Figure 6

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

For those that identified themselves as a Manager or Director of MSLs in the U.S., 45% of respondents were female versus 55% male. (Figure 7) For the global data, it was 39% female versus 61% male. (Figure 8)

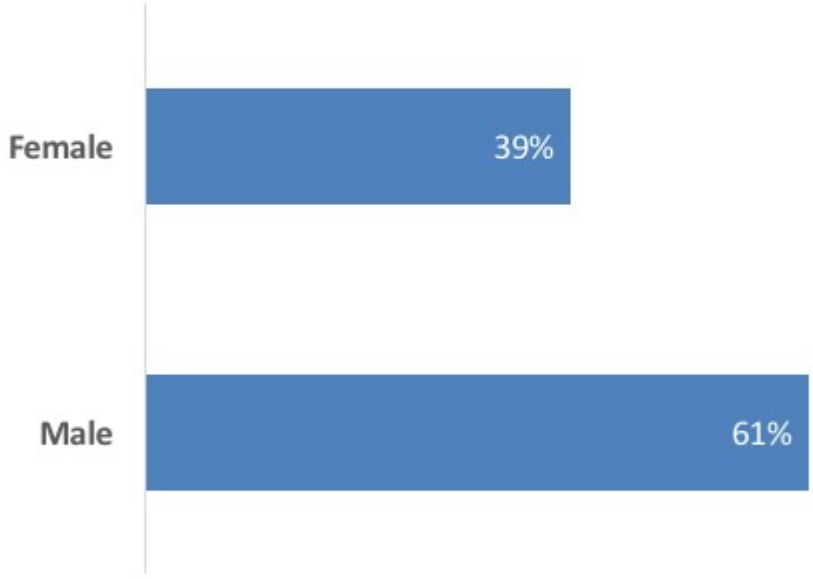
Those that answered "Yes, I manage MSLs" and reported their role as "Manager / Director of MSLs (or equivalent title)" by gender (U.S.)

Sample Size: 62 (U.S. Data)

Figure 7

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Those that answered "Yes, I manage MSLs" and reported their role as "Manager / Director of MSLs (or equivalent title)" by gender (Global)



Sample Size: 132 (Global Data)

Figure 8

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

While the gender pay gap for MSLs in the U.S. was just over 5% (Figure 1), for MSL managers in the U.S. the gender pay gap was about half that size at 2.7%, with males being paid on average $5174 more annually (Figure 9). This dollar difference is not statistically significant.

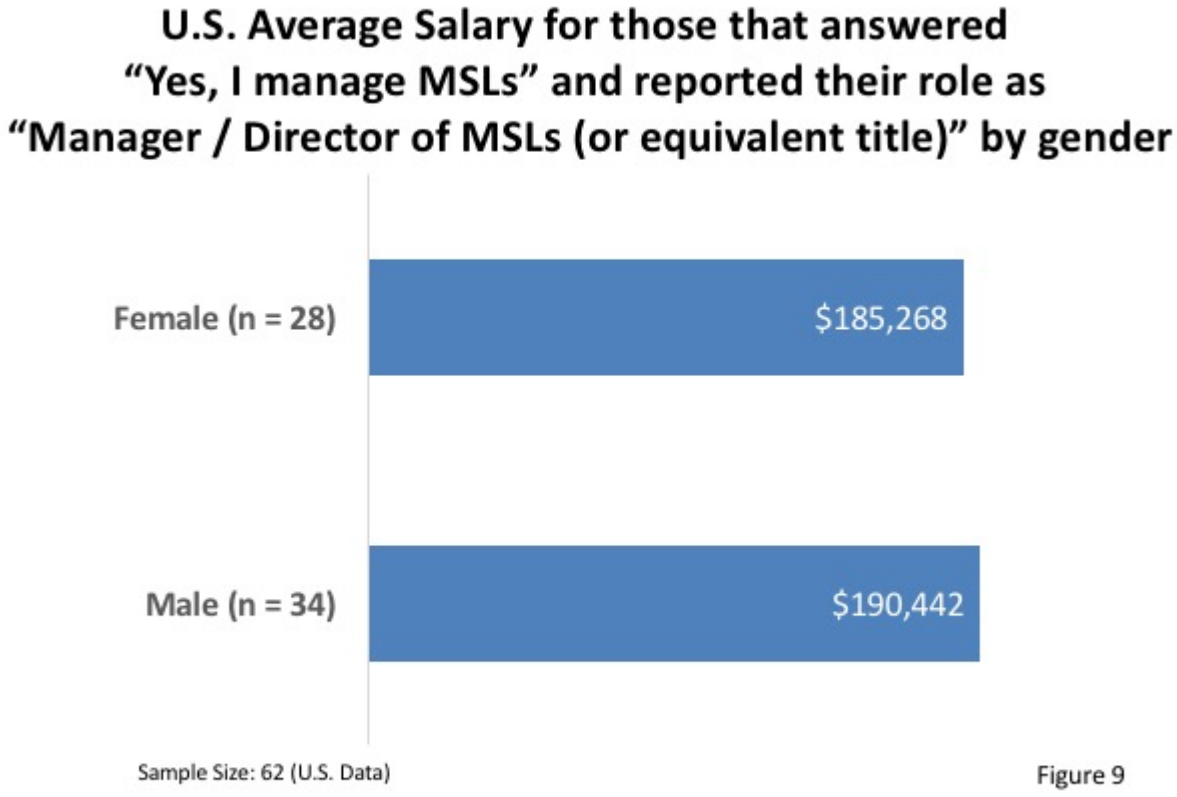


Figure 9

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

In stark contrast to all other gender pay gap differences in this study, the gender pay gap was reversed for MSL managers, with female managers being paid 11.2% or $16,200 more per year than their male manager counterparts (Figure 10). However, this dollar difference is not statistically significant.

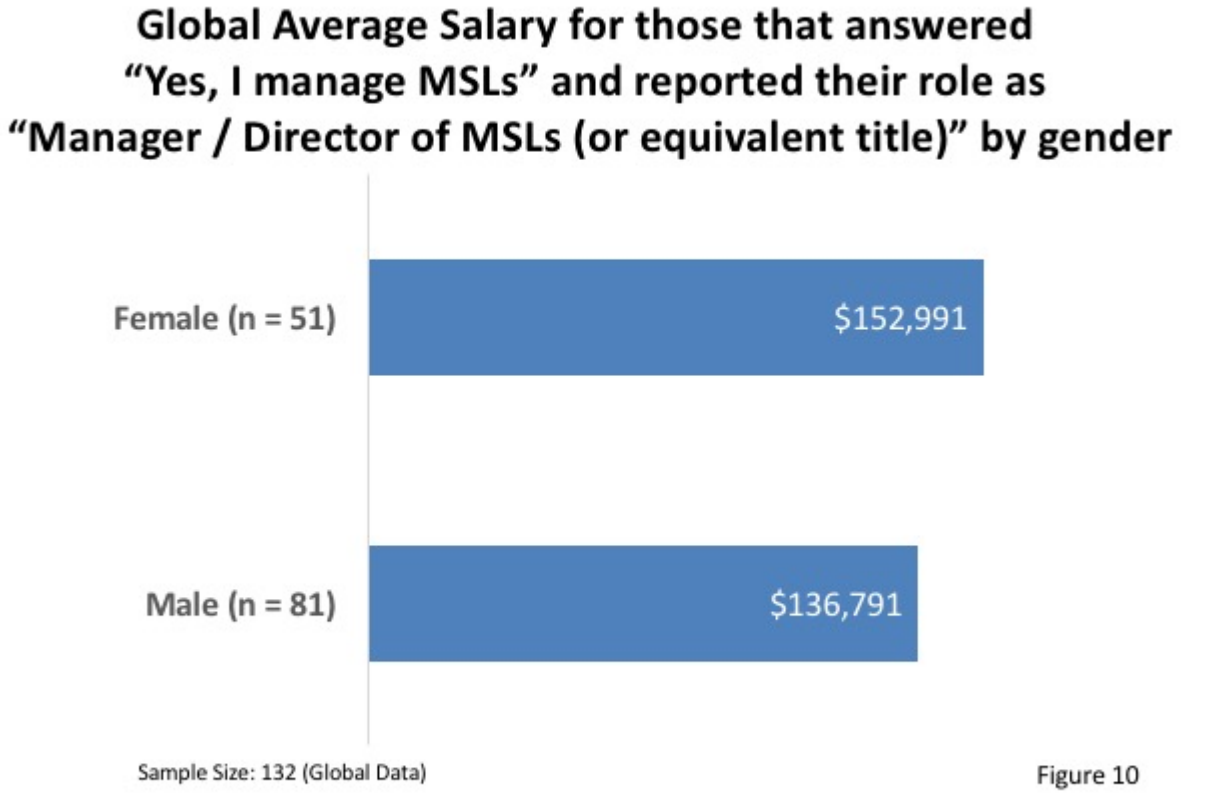


Figure 10

2015. MSL Salary & Compensation Survey. *Medical Science Liaison Society*

Conclusion

The objective of this analysis was to identify if pay gaps based on gender existed among MSLs and MSL managers. Significant pay gaps have been identified in various other professions within healthcare and the pharmaceutical industry, including an 11% difference for pharmaceutical sales representatives (11), a 9.9% difference for biotech sales reps (12), and an 18% difference for physicians. (10) While there are many potential reasons for gender pay gaps that have been cited in other studies for other professions, these variables were not evaluated in this study.

Although there are many important factors to consider in the successful recruitment and retention of staff, salary remains one of the most significant. The 2015 global survey on salary and compensation levels for both Medical Science Liaisons (MSLs) and MSL Management conducted by the Medical Science Liaison Society revealed gender pay gap differences for the first time among the MSL profession.

The results of the 2015 MSL Salary and Compensation Survey reveal that although gender pay gap differences were observed in all of the groups evaluated in the study (MSLs in the U.S. and globally, MSLs with less than one year of experience in the U.S. and globally, and MSL managers in the U.S. and globally), only the difference between male and female MSLs in the U.S. was statistically significant (Figure 1). Whether apparent gender pay gaps reflect salary differences due to other MSL characteristics (company type, academic background, therapeutic area, years of experience, etc.), and what is causing any actual gender gaps (backgrounds, negotiating styles, etc.) are all worthwhile topics for future research.

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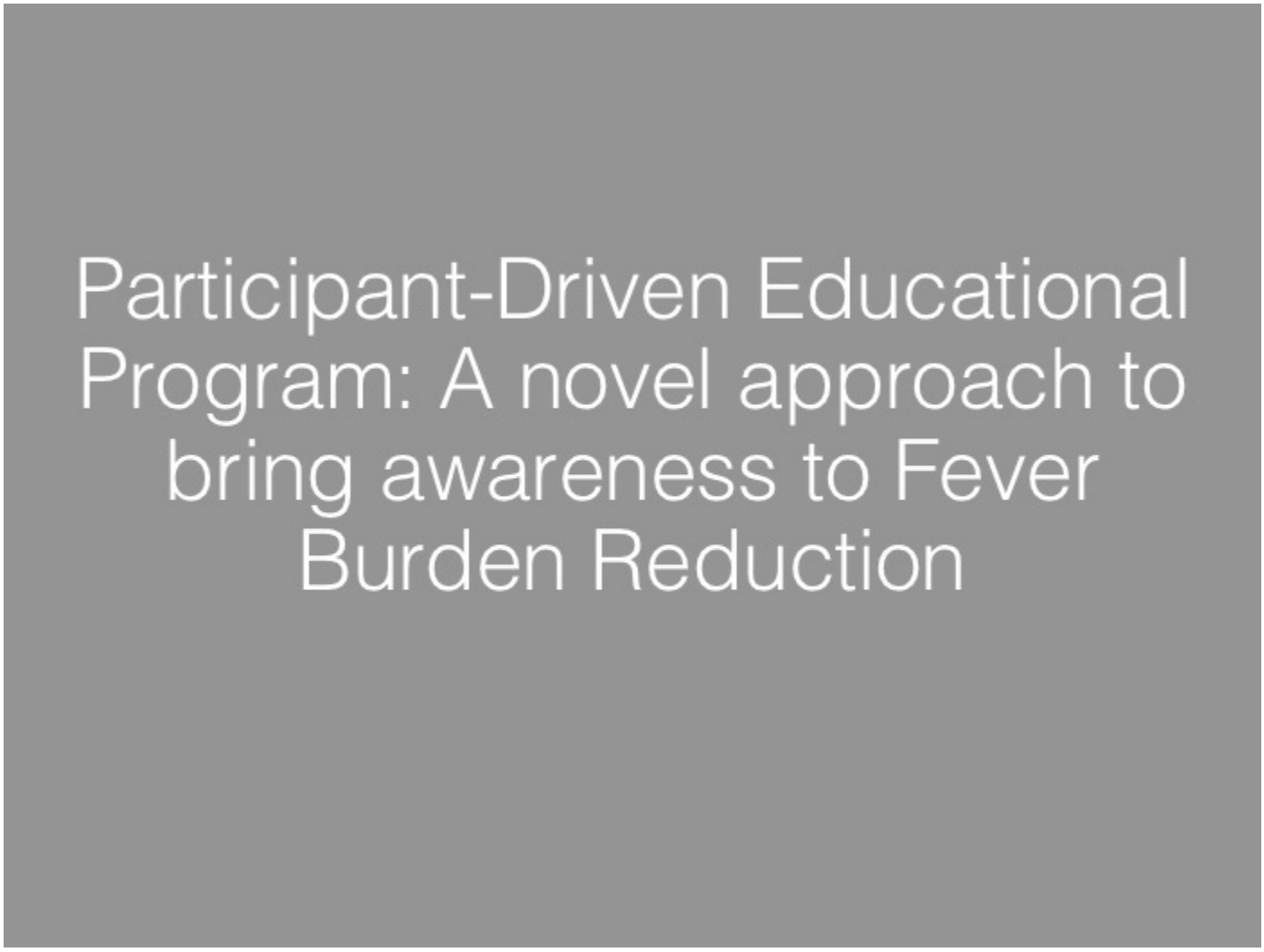
Participant-Driven Educational Program: A novel approach to bring awareness to Fever Burden Reduction

| Mar 2016



A Medical Science Liaison Approach in connecting with Key Opinion Leaders

Participant-Driven Educational Program: A novel approach to bring awareness to Fever Burden Reduction

Abstract

Successful, long-term thought leader relationships are forged through a pharmaceutical or medical device company's ability to create mutually beneficial relationships with top opinion leader candidates. Primarily, the most lucrative thought leader relationships are steeped in cutting edge scientific research which helps the company advocate its treatments, while at the same time aiding the physician in gaining more recognition and influence in the therapeutic area.

Medical Science Liaisons (MSLs) provide the crucial link between the company and the thought leaders. Specifically, the participant-driven educational program, which is a novel approach to connect a company with influencing Key Opinion Leaders (KOL) and participants at major conferences. In many organizations, MSLs educate clinical peers about the latest scientific developments and treatment guidelines affecting a specific therapeutic area. In addition, MSLs are sometimes called on to provide summaries of recent scientific congresses, make formulary presentations, or address unsolicited efficacy or safety questions. MSLs may also facilitate educational or research grants submissions or be asked to organize regional advisory boards. The services provided by MSLs are quite varied and are continually evolving (Williams).

MSLs are organizational leaders, organizational representatives, and scientific professionals. As such, they are required to align and establish relationships with selected KOLs. The process of relationships building should be conducted and documented in a manner that is both beneficial and transparent with a focused aim. The value of a participant-driven education program is to gain insight into the clinical care gap, knowledge gap, and scientific gap to assist in direct support of an organization and its goals (1).

Goal

The goal is to establish a collaborative community that has the potential to create an essential level of awareness and to set new expectations regarding a standardized methodology of care for patients. The Guidelines from the American Heart Association (AHA) serve as the markers or triggers to identify best practices. The identification of the problem of not controlling fever has increased mortality rate and has contributed to long term disability. A consideration of these guidelines elucidates both the importance of timely management and the necessity of formulating practice changes that will result in better outcomes (1).

Scientific Area

The result of temperature management in critically ill patients is the reduction of fever development in various types of neurological injury, injuries which are associated with increased risks of adverse outcomes (2). Due to the negative effects of fever, lowering an acutely elevated body temperature might improve the prognosis of patients with stroke. These measures include giving antipyretic medications and actively controlling the patient's temperature (American Stroke Association Stroke Council, Guidelines for Early Management of Adults with Ischemic Stroke) (3). The development of a collaborative community is necessary to create change, with special emphasis on transforming care and reducing the long-term consequences of neurological damage and long-term disability (1).

Fever was found to be strongly associated with an increased length of Intensive Care Unit (ICU) stay and higher mortality rates with worsened overall outcomes (4). Collectively, a meta-analysis presented the same results. In each of the outcome measures evaluated, the meta-analysis indicated that fever/higher body temperature was significantly associated with deleterious outcomes, higher mortality rates, greater disabilities, worsened functional outcomes, greater severities, and longer stays in the hospital and ICU. These results indicate that the association of fever with poorer clinical outcomes is present in all types of neurological injury (ischemic, hemorrhagic, and traumatic). It was observed that fever was consistently associated with damaging effects (5).

The identification of the problem of not controlling fever has shown an increased mortality rate and has contributed to long term disability. Fever, a temperature in excess of 38.3°C, occurs with an incidence of up to 70% in neurologically injured patients and it is usually not an isolated event, but rather a sustained response that can linger for as long as two weeks after injury (4). This is a problem that needs to generate more awareness and aggressive treatment in the hospital system. Best practices for fever burden management are not consistent, and, to a degree, are basically disregarded in clinical and research literature. Presented are a few references in literature that show that established fever is indeed associated with neurological deficits or secondary injuries.

The inconsistency in practice can complicate the achievement of best practices and other solutions regarding fever control. Healthcare providers should be the first to recognize this need and to embrace the continuous search for providing quality healthcare services. Fever exacerbates brain damage and is associated with worsened outcome in patients with aneurysmal subarachnoid hemorrhage (SAH) (6). Preliminary data suggests that active fever control is a reasonable therapeutic strategy after SAH. (7) Fever itself may increase Intracranial Pressure (ICP) (8).

Group Dynamics and Change in Medicine

Groups are both a pervasive part of modern life and cultivators of buy-in. The team design should be comprised of a formal group of professionals that have the capabilities to formulate a change. The requirement specifies that there must be some form of information exchange or communication between these individuals. This information must be disseminated to other professionals outside the group (1). The final requirement is that the group be formed to accomplish a common goal (9). The thought leader's goal among the group is dedicated to reducing neurological damage, reducing long-term disability, and setting directives for care.

The approach for a participant-driven network of professionals is to work to accomplish a common goal and to retain interest. Recognized objectives must align with the projected goal, and secondary goals as well, if applicable. An organization grows by acquiring knowledge, distributing this knowledge, and interpreting information in a manner that results in learning, adaptation, and change. These aspects subsequently become part of that culture (9). The meeting needs to have a platform led by two or three associated members: a CNS and a physician champion. The content is specific to fever control, projected expectations, and how the realization of this goal will be obtained (1).

Background

A participant-driven educational program using a Meet-the-Expert format is an innovative educational strategy that is focused on the learner. The purpose of such a program is to address clinical and organizational needs and issues encountered by hospital clinicians, especially those caring for patients undergoing fever control. Unsolicited questions from the participants were used to develop a curriculum and also to examine the barriers of TTM implementation in neurocritical care units around the United States. The educational format of the program also encouraged participants to have individual conversations with the experts both before and after the program. In order to help guide the expansion of fever control in US neurocritical care units we relied on a strategy of amalgamation, combining expert opinions with previously reviewed literature during the curriculum development process.

According to Weimer et al, “the transformation …. of classroom experiences requires a fundamental shift in how instructors approach teaching and learning, moving from an information-transfer, teacher-centered model to one that is concept-focused, learner-centered, and collaborative” [10]. To facilitate the discussion and creation of the agenda, program participants pre-submitted two questions that could provide jumping-off points for the continuation of discussions at the bedside during a Targeted Temperature Management (TTM) case. These questions, which were either clinical or organizational in scope, were placed into different categories upon initial acceptance. They were then given to a panel of nationally recognized experts in the field of Neurocritical Care for verification and review. Members of the lead faculty divided and assigned the verified topics among three other faculty groups, all of which were selected based upon their experience and individual contributions to the science of fever control. The contributors in the way of science possessed numerous arrays of special designations. Among the aforementioned are Key Opinion Leaders (KOL), TTM users for the purpose of neuro-protection in neurocritical care patients, world renowned speakers, authors, and educators on relevant subject matter, and active users in the critical care arena.

Most attention has heretofore been directed at the clinical utility in the neurocritical care patients, specifically those with relation to TBI, SAH, acute ischemic stroke, and fever control. Fever is of special significance according to the prevailing literature as it has a 70% rate of (co)occurrence in a number of the previously mentioned disease states [4,11-14]. However, there is limited evidence at present to specifically incorporate the application of TTM in such conditions; but through the lens of historical context there is more than enough evidence, especially insofar as previously reviewed patient care cases are concerned, to demonstrate how imperative the delivery of a timely educational message is for the greater benefit of improving patient care. An educational goal for this program was the engagement of clinicians in the critical analysis and anticipation of the needs of patients while providing resources for their individualized questions.

Design and Setting

The primary targets for the program were bedside clinicians who have direct care to a patient. Though an email invitation was sent to participants of the conference, RSVPs were limited to the first 50 due to logistic issues. The attendees from the last 4 conferences numbered in the area of 6,000 to 7,400. Anticipating that we would exceed the limit capacity of 50, we asked every prospective attendee to complete two questions in order to determine whether or not they met the criteria for acceptance. The questions are as follows: (1) what is your involvement in your TTM program? and (2) Name some reasons why you should be chosen. In the healthcare setting, the ability to work as part of a team is of paramount importance, for it encourages team members to engage in often difficult implementation practices. The smaller program sizes provide participants with a more relaxed atmosphere in which they can actively build on the expertise and talents of the group as a whole [12]. This type of informal setting can help students to acquire a greater appreciation for the role of others through group problem solving exercises and open discussions, both of which promote collaborative medicine. Groups can consist of as little as four or as many as 25 people; however, in these situations, strong leadership is needed to ensure that the group interacts appropriately and develops their interpersonal skills [15]. Perhaps most importantly, the size of the group is not as significant as what the group actually accomplishes, as a well-defined structure, taken in conjunction with the skill of the organizer as facilitator, are key to the effectiveness of small group sessions [16].

Participants

A total of 70 RSVPs were received for the “Meet-the-Experts: a participant-driven program held during a National Conference. There were 43 attendees (43/70, 61%), 2 cancellations (2/70, 3%), and 25 no-shows (25/70, 36%). The total number of participants was 51, including 8 walk-ins. As no demographic information was obtained from the walk-ins, their information was not included in the analysis of data. The majority of the participants were staff nurses (26, 61%), followed by nurse educators and nurse managers. The most common unit in which attendees were employed was a mixed ICU that admitted neuro patients. There were 27 hospitals that were represented with 12 hospitals that had 2 or more participants in attendance.

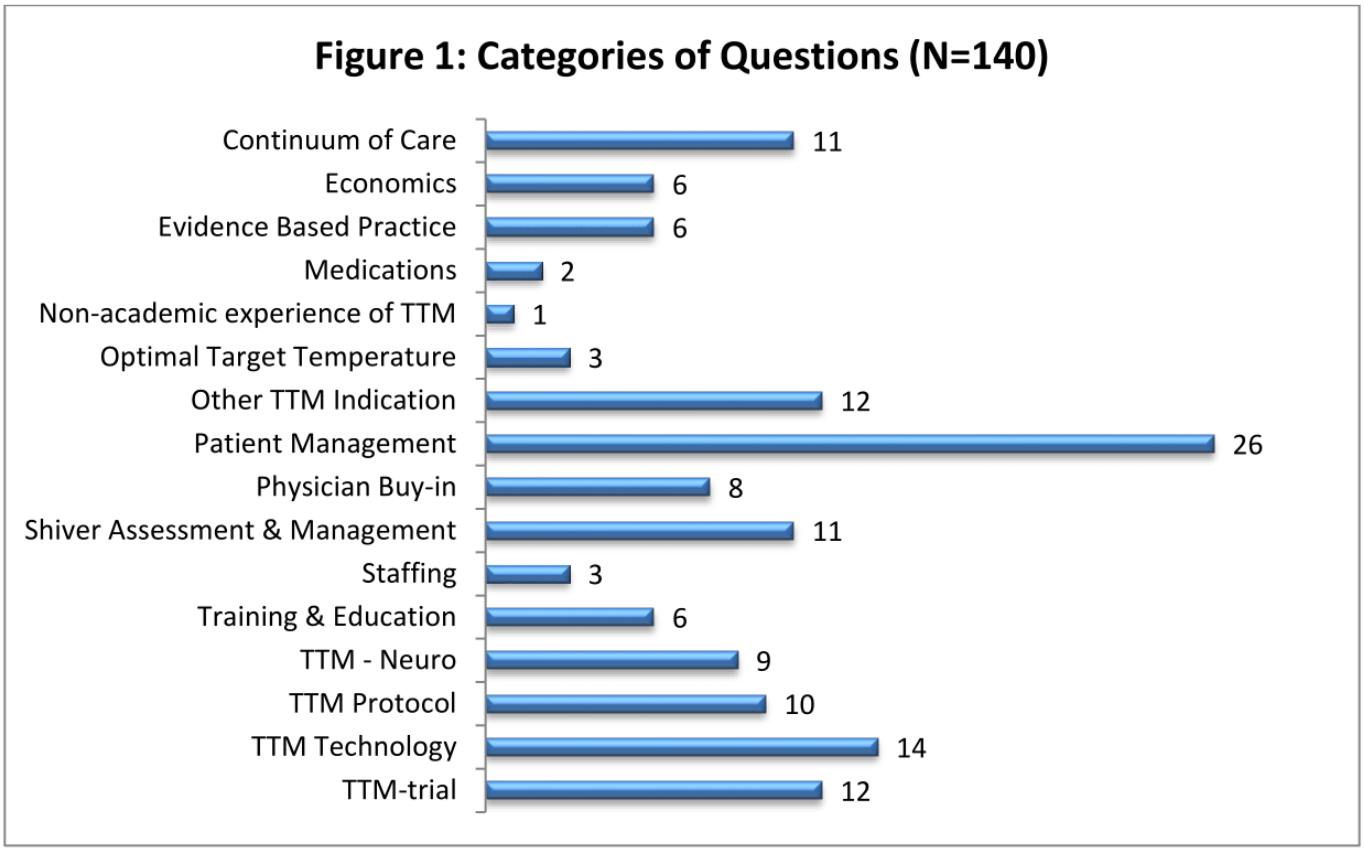
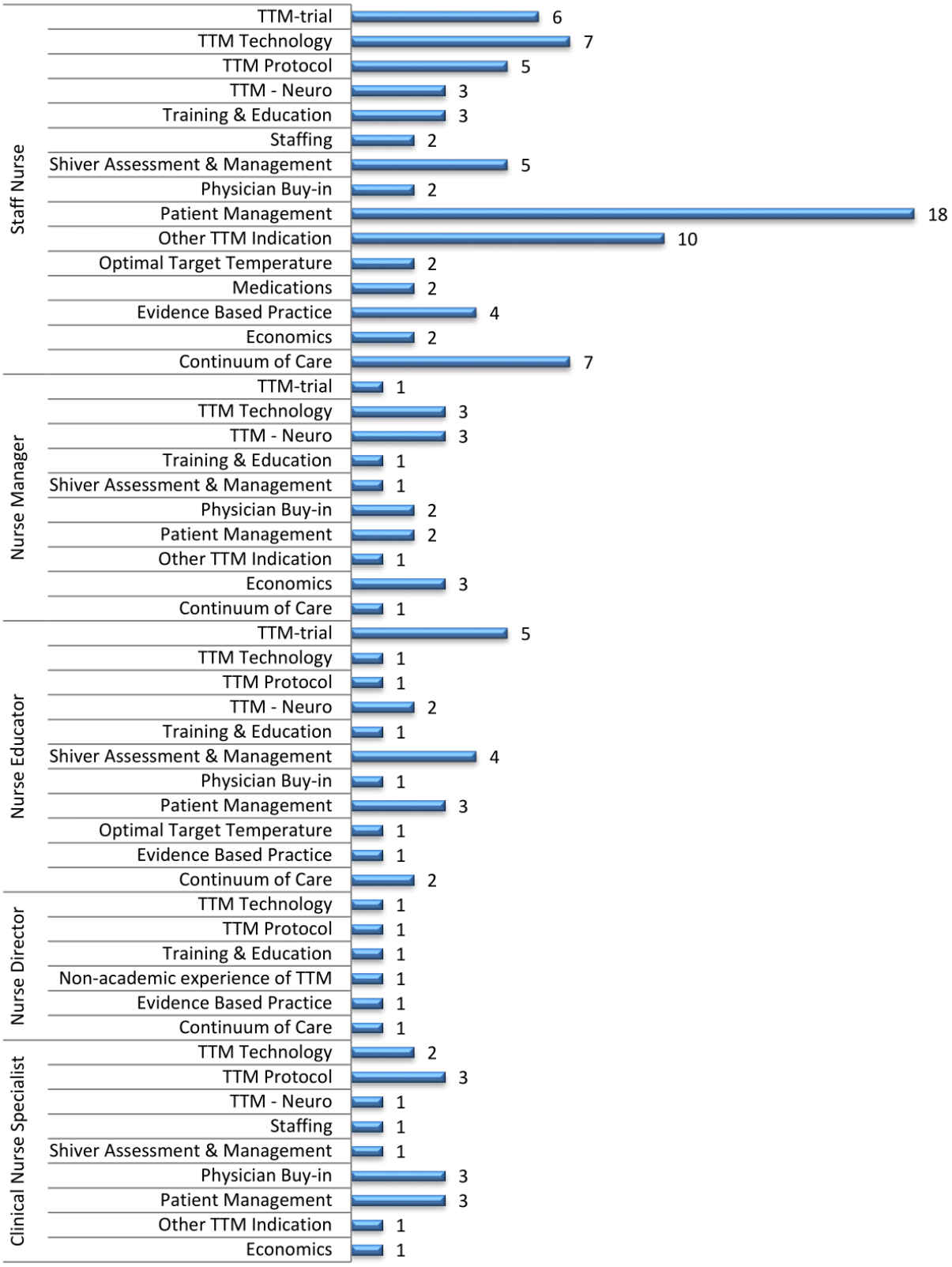
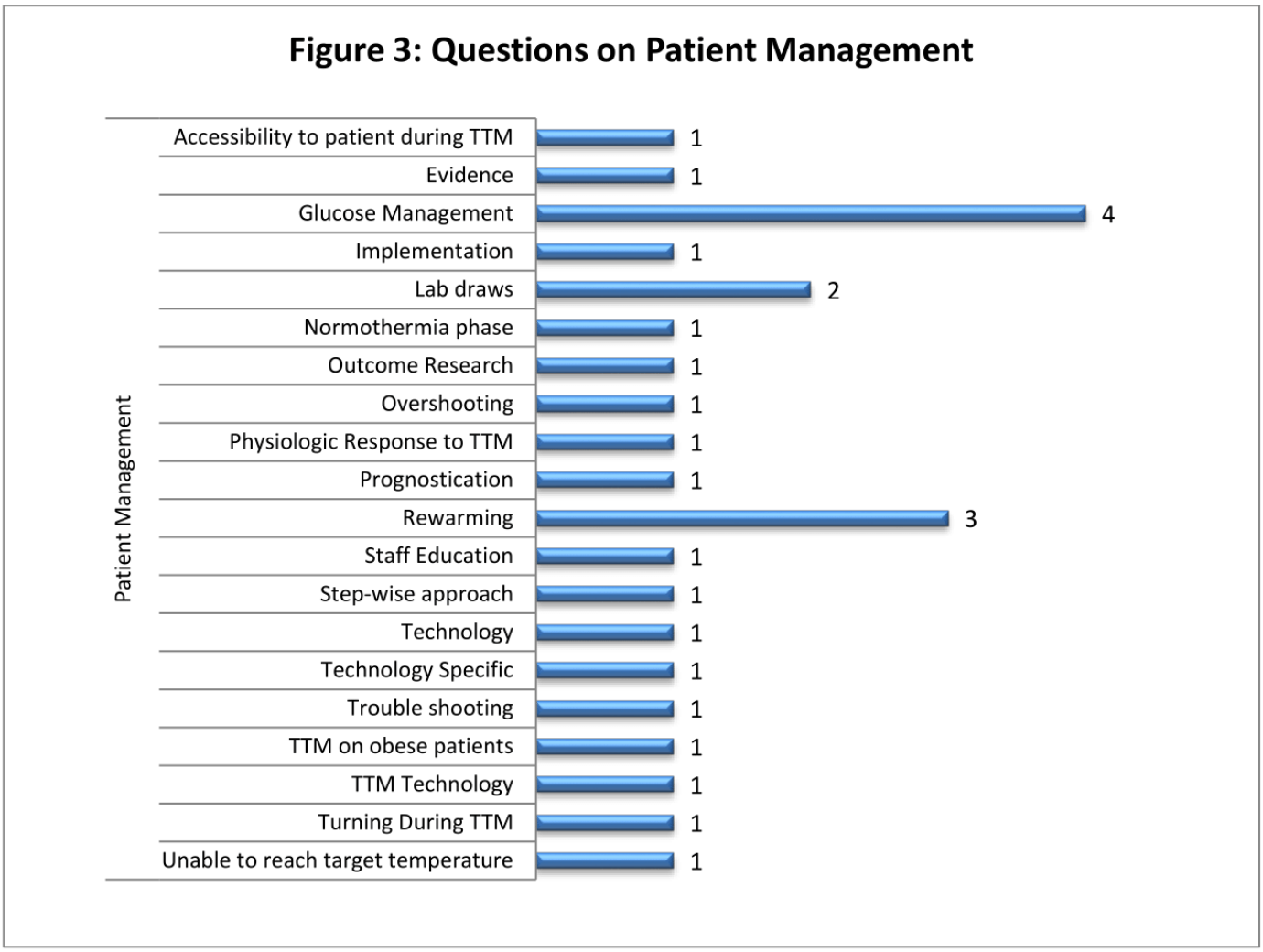


Figure 1: Categories of Questions (N=140)
Continuum of Care
11
Economics
6
Evidence Based Practice
6
Medications
2
Non-academic experience of TTM
1
Optimal Target Temperature
3
Other TTM Indication
12
Patient Management
26
Physician Buy-in
8
Shiver Assessment & Management
11
Staffing
3
Training & Education
6
TTM - Neuro
9
TTM Protocol
10
TTM Technology
14
TTM-trial
12

Figure 2: Role-Specific Questions





Post-Event Feedback Survey

A SurveyMonkey® post-event feedback survey link was created and emailed to the participants. The questionnaire consisted of 29 questions. The 29 questions were composed of attendee demographics (questions 1-3), speaker evaluations for 3 faculty members (questions 4-9), overall activity (questions 10-11, 20-24), educational needs (questions 12-13), the program itself (questions 14-16), program administration, facilities, and logistics (questions 17-19), and future programs (questions 25-29). An email reminder was emailed to the participants on two additional dates. SurveyMonkey is an online survey tool that provides data collection and analysis. Thirty-one participants completed the survey (31/41 (76%)) while ten did not (10/41 (24%)).

Educational Needs Questions: These questions serve as the Clinical Care Gap

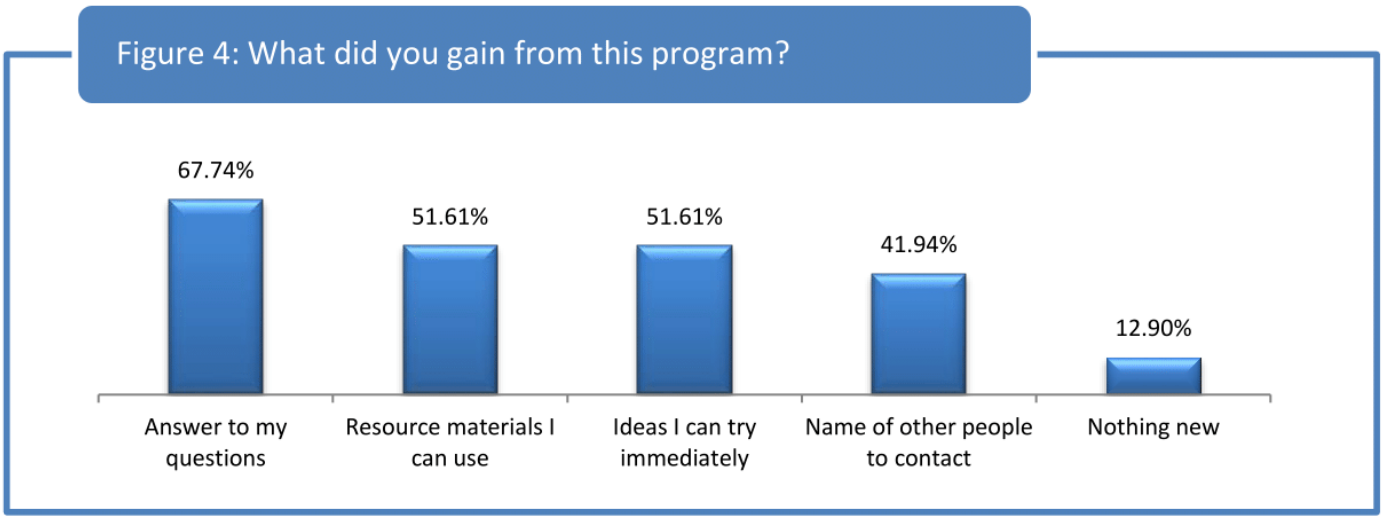
Table 7: Most Challenging in Practice Area
•Shivering •Prevention and Management •During rewarming phase •TTM-Trial •Dose-related - 33°C for most severe anoxic patients •Neuromonitoring •Protocol adherence •Normothermia in neuro patients •Continuum of care •Data collection •Guidelines

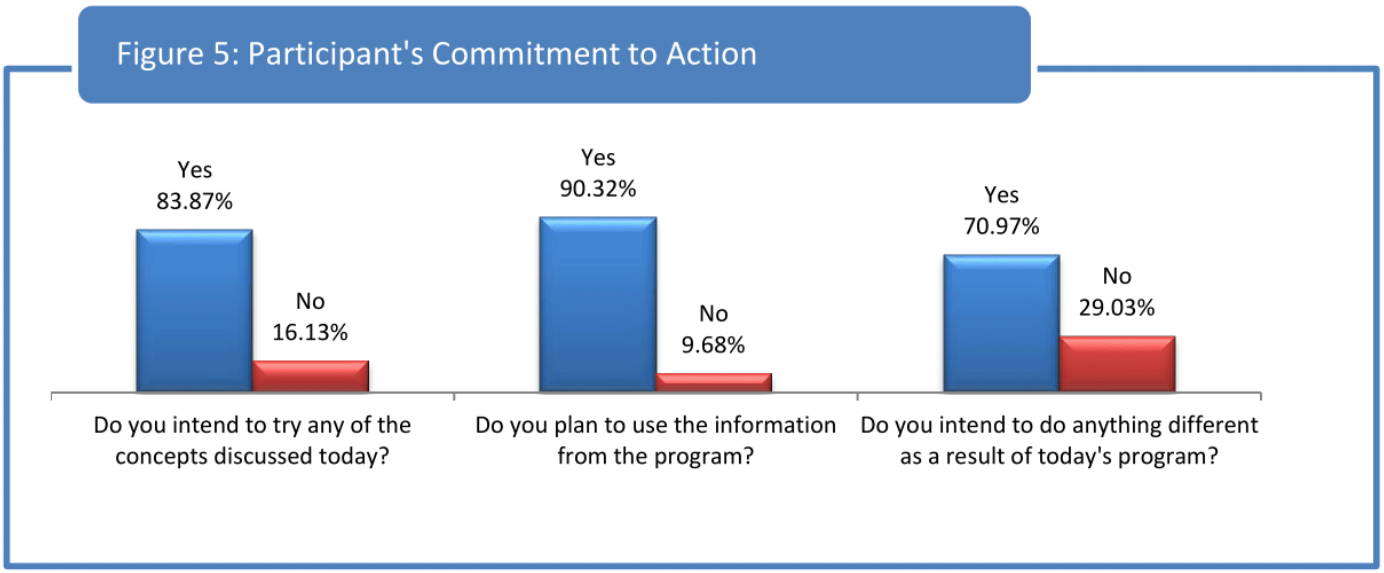
Table 8: Topics of interest
• Current and future research • Pharmacological approach to shiver management • Glycemic management in hypothermia • TTM in neuro patients • Data to support effectiveness of higher (35°C) target temperature • EEG monitoring and role of nurse • Fever control in neuro and trauma population • Normothermia protocol • Patient management of the obese patient

Discussion

The translation of research into clinical practice will require clinicians in the field to more fully understand the benefits, implications, and ramifications related to the use of strict fever control. With the absence of scientific guidance, dialogue, and education; the bridge to close the clinical care gap from research to clinical practice remains nebulous. From the results of a literature review and the corresponding questions clinicians suggest that clinical education is in order. Moreover, given the tenure of clinicians, additional professional development resources may be needed for the adoption and implementation when innovative therapies are introduced as part of standard care protocols.

Overall Activity Questions:





Strengths and Limitations

- This is a regional trend and not a national trend as defined by geographical considerations. Thirty-five out the 51 (69%) attendees practice nursing in the state of California where the California Department of Public Health has a Nurse-to-Patient Staffing ratio regulations.

Observations and Recommendations

- The program demonstrates the feasibility and value of a participant-driven educational program using Meet-the-Expert educational strategy in a therapeutic space where consensus is a challenge.
- A 6-month follow-up should be done to assess where participants are in the process of adopting information received from the Meet-the-Experts program.
- A similar program should be conducted next year at the conference to compare regional trends in clinical and organizational issues in caring for patients undergoing TTM.

Conclusion

In conclusion, **c**urriculum development and instructional management are at the core of the educational process and central to an educational program. These are some of the key features of the scientific infrastructure that allow this type of pedagogy to be made deliverable in an educationally executable format. Here, a participant-driven educational program using a Meet-the-Expert format provided an innovative learner-focused educational strategy that gauged the needs of the participants and care

givers who link the treatment platform to this unique patient population. The implications of this forum are that building dialogue and promoting discussion will transform TTM neurocritical care into a standard of care and medical practice. There is a need for the implementation of small engagement programs as a complimentary educational strategy in medical education. Moreover, there is an immediate need for leadership programs for the purpose of arming future medical personnel with the tools to manage modern medical practice by means of the educational methods delivered at the national conference.

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Overview of Safe Harbors and Regulatory Compliance and the Impact on MSLs

| Mar 2016

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During the past decade regulation has impacted the medical device and pharmaceutical industry; for better or worse this influence continues to change the environment. It is imperative that company executives stay in front of, and react to, increased complexities of change in the healthcare environment brought on by regulation. Observant business strategies are also necessary to eliminate the risk associated with common themed infractions. One such infraction is off-label promotion, as this remains a prime focus of government investigations within the medical device and pharmaceutical industry.

Alarm has mounted among government policymakers, patient advocates, physicians, and leaders in the industry that influence clinical practice, medical education, and medical research (1). The aforementioned have been the nexus of some practices of off-label promotion. Government enforcement actions, congressional hearings, and press coverage have generated intense scrutiny of the dubious financial relationships and questionable industry practices that persist in this area. With these actions patient care and medical advancements may suffer at the plight of over-regulation. By and large, the medical industry targets physicians with promotional efforts – these physicians often serve as the doorkeepers for medication prescription and medical device use. Companies also enter into financial agreements with physicians for consulting; in which these physicians speak at national conferences and provide clinical and marketing research as a professional service (2).

On some occasions off-label information is presented at conferences. There are two different scenarios or circumstances that surround such scientific meetings. First, that the presentation is regulated and under the control of the manufacturer. Second, that there is no manufacturer control. In order for the presentation to be lawful, the conference must be independent from the

manufacturer. This means that a physician who presents off-label information must not be a representative of the manufacturer. Further, the manufacturer must not have influence over the conference speakers content, attendees, or have any sponsorship role at the educational program (3).

In determining independence, the FDA will consider the sponsor's control over the speaker and content, meaningful disclosure, and the manufacturers relationship with the speaker. As a side note, the federal Food, Drug and Cosmetic Act (FDCA) includes a practice-of-medicine exemption that allows physicians to use devices in any manner they see fit. This also includes presenting off-label information to members of the general public – such as those in an audience at a conference. This is permissible only if this is not a controlled event. Finally, controlled communication should be regulated as promotional material and be consistent with the intended use. This would indicate that rules applicable for dissemination of written material, appropriate location, interaction with healthcare professionals and the speaker's agreement must be followed (3).

Under the final guidance, the FDA asserts regulatory authority over any scientific or educational program supported by a pharmaceutical or medical device manufacturer in which the content of the program pertains to the sponsoring company's products or competing products, and the program is intended to, or does, reflect the direct or indirect influence of the supporting company. The agency disclaims any regulatory authority over programs that are both independent and non-promotional per 62 Fed. Reg. at 64,074.

Educational speaker programs at conferences that are not independent, or may reflect some influence by the supporting company, "are not per se illegal, but they are subject to regulation" as the final guidance makes clear. (4) In other words, these programs must pertain only to approved indications for the products being discussed. Again, the emphasis here can be summed up with a single word: "independence." If a scientific or educational program that pertains to research concerning potential new uses of a medical product is intended to be and is truly independent of any direct or indirect influence by the sponsoring company, the guidance suggests that the agency will not interfere. In contrast, the FDA will view any discussions of off-label uses that aim to influence from the sponsoring company as violations of the FDCA. The majority of the guidance is devoted to enumerating a lengthy and nonexclusive list of factors that the agency will weigh or balance in an unspecified manner to evaluate whether a program is truly independent (4).

> The federal Food, Drug, and Cosmetic Act (FDCA) prohibits the "adulteration or misbranding" of any device or drug. Two major points stand out. One, under the law, a drug or device is deemed misbranded if its label does not bear "adequate directions for use." Two, because the label on a device or drug relate only to approved uses, when either is promoted off-label, its label does not bear adequate directions for the new off-label use. Therefore, the drug or device is misbranded. In order to obtain FDA approval, the manufacturer must obtain the safety and effectiveness of the product for its intended uses. Therefore, promoting a drug or device outside of its approved indications constitutes the introduction of an unapproved new drug into interstate commerce in violation of the FD&C Act, 21 USC Sec. 331 (d).
>
> The "intended use" of a drug or device refers to the objective intent of the persons legally responsible for the labeling of the product. This intent is determined by such persons' expressions or by the circumstances surrounding the distribution of the article including, for example, labeling claims, advertising matter, or oral or written statements by such persons or their representatives. (See 21 CFR 201.128 and 801.4.) The agency, thus, regulates products based not only on information provided "with" the product (approved professional labeling), but also based on information disseminated by or on behalf of manufacturers in other contexts, such as scientific and educational meetings and symposia, books, reprints of articles from scientific journals, in part because all of these activities/materials can create new intended uses for the products, which must be reflected in the approved labeling of the products, 21 CFR 201.128 and 801.4.

WHAT IS SAFE HARBOR

In some cases, an off-label use of a drug or device may be the medical standard of care. A failure for a physician to use a drug or device in an off-label manner may constitute medical malpractice. This is one reason the FDA allows companies to provide physicians with the following type of off-label information about unapproved uses. These include:

Scientific and medical journals. Manufacturers may provide physicians with scientific and medical journal articles that discuss off-label uses of a product. To be able to provide this information legally, companies must adhere to a strict set of rules developed by the FDA. In January 2009, FDA published "Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices" (often referred to as "Good Reprint Practices Guidelines.") Since that time an updated draft dated February 2014,

became available at ocod@fda.hhs.gov. These practices set forth the requirements for journal articles and the conditions under which they may be distributed. One can consult the FDA website for a copy of these guidelines.

Inquiries from physicians must be unsolicited requests for a company to respond to off-label uses. The response to any such unsolicited inquiry must be balanced—or include information about both the risks and benefits of the off-label use—and be commensurate with the scope of the question. It is not acceptable for sales personnel to encourage "inquiries" from physicians. Any inquiry must genuinely originate with the physician in order for the company to respond legally (6).

The purpose of establishing Good Reprint Practices was to describe the conditions under which medical or scientific literature concerning off-label use of a drug, biologic or medical device could be distributed without prompting the FDA to say the information misbranded a product that has an approved use. The Good Reprint Practices created a "safe harbor" for off-label use information that would otherwise be prohibited based on a misbranding charge. Manufacturers must adhere to the guideposts of "should" and "should not" when navigating within the safe harbor. FDA uses several factors to determine whether or not a medical or scientific journal article stays within the safe harbor. By following FDA's guidance on what a manufacturer should and should not do, the FDA will not use the dissemination of the reprinted medical or scientific article as evidence of a manufacturer's intent to promote and market an off-label use (6).

A manufacturer should consider the following before it disseminates a reprint of a medical or scientific article regarding an unapproved use according to the Good Reprint Practices:

1. 1.The article should be published by an entity with an independent editorial board with relevant expertise and objectivity.
2. The article should appear in its unabridged form
3. The editors, authors and contributors associated with the article are subject to full disclosure of a conflict of interest based on a publicly stated policy.
4. The article should be peer-reviewed under the publishing organization's established procedures.
5. The article should describe the information in the context of being derived from adequate and well-controlled clinical investigations.
6. The article should be disseminated with the product's approved labeling.
7. A comprehensive bibliography should be disseminated with information from other publications that is contrary to the results.
8. The article should not be used in conjunction with or associated with any other promotional literature or activity (6).

In recent years, most of the enforcement actions for off-label promotion have been focused on drug companies. However, the FDA, the United States Office of Inspector General (OIG), and the Department of Justice are increasingly paying attention to off-label promotion in the device industry and will receive the same level of scrutiny as the pharmaceutical companies. These are considerations for observant executives to consider while implementing business strategies within their own company.

References

1. N.K. Choudhry et al., "Relationships between Authors of Clinical Practice Guidelines and the Pharmaceutical Industry," JAMA 287, No. 5 (2002): 612-617; Association of American Medical Colleges (AAMC), Industrial Funding of Medical Education: "Financial Support of Continuing Medical Education," JAMA 299, No 9 (2008).
2. T.A. Brennan et al., "Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers, "JAMA 295, No 4 (2006): 429-433.
3. 62 Fed. Reg. at 64,074.
4. id.
5. 21 CFR 201.128 and 801.4.
6. The Food and Drug Administration (FDA) issued a revised draft guidance document in February 2014 entitled, "Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices." The guidance updates the draft guidance issued in January 2009 entitled, "Good Reprint Practices for

the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices." The Food and Drug Modernization Act (FDAMA) (21 U.S.C. § 360aaa) amended the Food, Drug, and Cosmetic Act (FD&C Act) to include the regulatory conditions under which a reprinted published medical or scientific article may be distributed by a manufacturer to healthcare professionals and related healthcare businesses. The regulatory issue continues even though the FDAMA amendment is no longer in effect.