Understanding Inquiry Escalation and Medical Response Document Review Processes

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Abstract

Background: The objective of this initiative was to characterize the escalation process involved in responding verbally to unsolicited medical inquiries that do not have a prepared response and to identify the functional areas involved in the review of Medical Response Documents (MRDs). Currently, there is variation in how Medical Information departments manage unsolicited medical inquiries for which a standard MRD does not exist. Additionally, there are differences in MRD review processes. **Methods:** A 17-question, multiple-choice, internet-based survey was sent to Medical Information departments at the top 50 pharmaceutical companies with operations in the U.S. **Results:** Nineteen (19) companies responded to the survey. When an unsolicited medical inquiry is first escalated for a verbal response, three (16%) companies require a Medical Director to respond. Two (11%) companies do not require MRDs to be reviewed beyond the Medical Information team; however, 17 companies require MRDs to be reviewed by a Medical Information Director (8; 42%) or a Medical Director outside of medical information (9; 47%). Legal and regulatory departments always review MRDs in four (21%) of the companies who responded. **Conclusion:** Medical Information departments require either a Medical Information Director or Medical Director outside of Medical Information to review escalated MRDs; however, verbal responses to medical inquiries can generally be handled by personnel within the Medical Information department and contact center.

Introduction

Currently, there is inter-company variation in how Medical Information departments manage unsolicited medical inquiries for which a standard Medical Response Document (MRD) does not exist. Additionally, there are differences in MRD review processes. In order to evaluate these differences, a 17-question, multiple-choice, internet-based survey was sent to Medical Information departments at the top 50 pharmaceutical/biotechnology companies.

Objectives

1. To characterize the escalation process involved in responding verbally to medical inquiries that do not have a prepared response.
2. To identify the functional areas involved in the review of MRDs.

Methods

A survey was sent to the top 50 pharmaceutical/biotechnology companies based on 2007 Global Pharmaceutical Sales[1]. The survey consisted of 17 multiple choice questions. Each multiple choice question included an optional answer of "other, please specify" thus allowing for a free text explicit response.

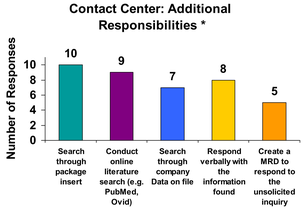
The survey was conducted electronically by Zoomerang™ Pro and was sent to survey-takers via e-mail with instructions that the survey be forwarded to an appropriate, qualified member within the Medical Information department. Qualifications for the survey-taker include: worked within Medical Information for at least six months, has been actively involved in responding to unsolicited medical inquiries, and has a complete understanding of the infrastructure and operating procedures within the company's Medical Information department. Only one individual within each company was allowed to submit the completed survey.

The number of responses for each question will vary because some questions allowed for multiple selections, and specific questions could also be bypassed depending on prior choices. The survey was conducted over a period of 21 days, beginning January 12, 2009.

Results

Of the 50 pharmaceutical companies contacted, 19 responded to the survey. Most companies (68%) use an internal group to run their contact center as the first point of contact for an unsolicited medical inquiry; the individual that first handles verbal requests for information is most commonly a pharmacist (84%). If a prepared response is not available for an inquiry, 53% (N=10) of companies require their contact centers to take additional action (Figure 1).

Figure 1



*Companies could choose more than one answer choice (N =10)

Results

Of the 15 (79%) companies that provide 24-hour coverage for medical inquiries, only one company (7%) requires a Medical Director to be on-call; the reason provided was that they have the latitude to offer additional data beyond what a Medical Information Specialist can provide. A Medical Director is defined here as an individual (either within or outside of the call center) having extensive in-depth clinical expertise in the therapeutic area and who has significant responsibility for managing the lifecycle of the product. The majority (73%) of companies use a health care professional from the contact center to provide 24 hour coverage.

Verbal Response Escalation Process

Before an unsolicited medical inquiry is escalated, 10 (53%) of the contact centers do additional research before escalating the inquiry to one of the following: Medical Information Team (2; 20%), within the contact center to another health care professional (4; 40%), a Medical Science Liaison (1; 10%), or a Medical Director (3; 30%) for a verbal response. A Medical Director is defined here as an individual having extensive in-depth clinical expertise in the therapeutic area and who has significant responsibility for managing the lifecycle of the product.

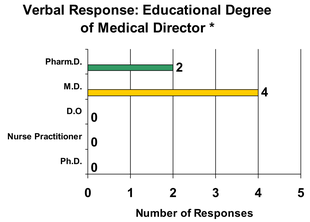
If the contact center is not responsible for performing additional research, all inquiries are either escalated to the Medical Information Team (6; 66%) or within the contact center to another health care professional (3; 33%) for a verbal response.

The most commonly provided reason an inquiry is escalated to a Medical Director for a verbal response is that they have the appropriate credentials to respond verbally without having to obtain approval from a superior (Figure 2). In the survey, the Medical Director has either a Pharm.D. or M.D. (physician) background (Figure 3).

Figure 2

*Companies could choose more than one answer choice (N=4)

Figure 3

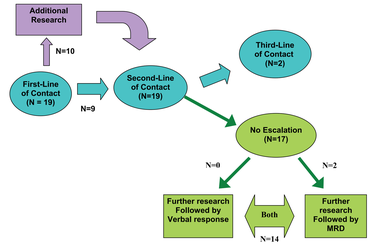


*Companies could choose more than one answer choice (N=4)

Results

In most companies (89.5%), there is no third-line of contact that responds verbally to an inquiry; instead, Medical Information is generally responsible for taking steps that involve the creation of a Medical Response Document (MRD) or verbal response (Figure 4).

Figure 4 - Escalation Process of Unsolicited Medical Inquiries



Medical Response Document Review Process

Two (11%) companies do not require that an MRD be reviewed beyond the Medical information team; however, 17 companies require MRDs to be reviewed by a Medical Information Director (8; 42%) or a Medical Director outside of medical information (9; 47%). A Medical Director is defined here as an individual, outside of Medical Information, having extensive in-depth clinical expertise in the therapeutic area and who has significant responsibility for managing the lifecycle of the product. Few companies require a mandatory review by regulatory (21%) or legal (21%) departments for Medical Response Document (MRD) approval (Figure 5). The most common reason for obtaining a Medical Director's approval was to ensure that all relevant data was included and interpreted correctly (Figure 6).

Figure 5 - Medical, Legal, and Regulatory Review Processes of MRDs

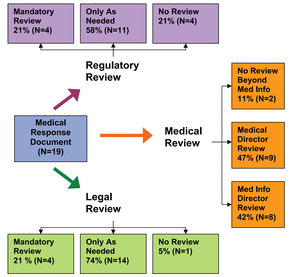
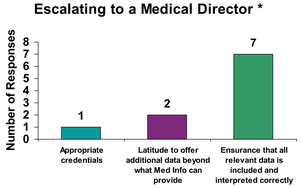


Figure 6

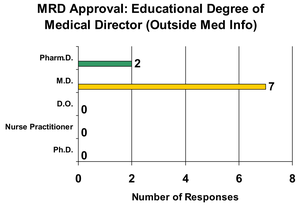


*Companies could choose more than one answer choice (N=9)

Results

In those companies where a Medical Director outside of Medical Information is required to review an MRD, the educational degree of this individual is either a M.D. or Pharm.D. (Figure 7).

Figure 7



(N=9)

Discussion

The survey was successfully sent to 48 pharmaceutical companies; there were two companies that did not have a U.S. contact number. Also, three companies sent notification that they were unable to participate in the survey due to company-specific regulations. After a 3 week survey period, 19 companies completed the survey. Response to the survey may have been limited by company regulations with respect to proprietary information; some companies may have been unwilling to share this information and did not send notification of their decision. Additionally, certain Medical Information departments may not have prioritized the survey task due to workload and time constraints. Lastly, the length of the survey may have been a deterrent for responding to it by our deadline.

The role of the contact center is extensive and broad in that they are involved in doing additional research, providing 24-hour coverage, and having escalation procedures within the contact center to provide verbal responses. Medical Information teams are widely used as the second-line of contact for both verbal responses and creation of MRDs. Overall, the MRD review process is not entirely dependent on the review/approval from any particular functional group, which includes legal, regulatory, and a Medical Director outside of Medical Information. Based on the results of this survey, the Medical Information department, in collaboration with the contact center, is self-sufficient for the most part.

Of the companies that utilize a Medical Director outside of Medical Information to approve MRDs, it would appear that the most common reason is for quality assurance. Of note, pharmacists are very much involved at every level of medical inquiry escalation; this includes the role of Medical Director who reviews MRDs and has verbal response responsibilities.

Conclusion

The escalation and immediate response to unsolicited medical inquiries is largely dependent on health care providers at the contact center and in the medical information department, and seldom requires involvement from a Medical Director. Medical response documents are commonly reviewed by either a Medical Director or Medical Information Director to obtain approval, and commonly require regulatory and legal review on an as needed basis only.

References

1. Pharmaceutical Executive: Top 50 Companies (May 2008). *The Pharmaceutical Executive* page. Available online at: http://pharmexec.findpharma.com/pharmexec/data/articlestandard//pharmexec/302008/531367/article.pdf. Accessed December 1, 2008.