Evaluating the Quality of Adverse Event Reporting Through the Medical Information Call Center

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Background

- By evaluating the comprehensiveness of adverse event (AE) reports received through the medical information call center (MICC) channel, the medical information community can evaluate if the questions asked during a report are eliciting the information currently deemed necessary to determine correlation and causality.
- If reporters are knowledgeable and willing to provide a report of high quality, perhaps this would be reflective to additional questions, such as those involving the patient's medical and medication history. In turn, this may help to further isolate the cause for the AE and lead to the proper course of action for patients and providers.
- In the case of low quality reports, the questions that reporters are unable or unwilling to provide a response to can be identified and investigated.
- This study aims to fill the current gap in knowledge and generate discussion on ways the medical information community can enhance the dialogue exchange that takes place during an AE report.

Objective

The objective of this study is to evaluate the quality of AE reports received by a MICC and to determine which reporter type provides the highest quality report.

Method

- A literature search of MEDLINE was conducted to determine the current understanding of the research topic. Key words included medical information call center; adverse event reports, quality and/or assessment.
- No relevant citations were identified.
- A Rutgers IRB approved retrospective analysis was conducted on a randomized sample of 10% of all AE reports received by a MICC during the month of October, 2018.1 AE reports were de-identified prior to evaluation of the study data.
- Voluntary responses to 16 questions (above) identified by the investigators in necessary for the evaluation in correlation and/or causality were assessed.2

Results

- A total of 1376 reports during a 30-day time span qualified for the study. 138 reports (10%) were randomized and included in analyses. 67 (48.5%) reports contained at least one field response (Figure 1).1
- Consumers were the source of 25 (37.5%) of reports with at least one field response and healthcare reporters, 41 (60.2%). One report (1.3%) was from an unknown source, classified as “other.”1
- The average score of all reports was 1.78. Amongst reports containing at least one field response, the average score was similar amongst consumers and HCPs (Figure 2).1
- Response rates varied across the question set (Figure 3).2
- The highest response rates were to questions regarding AE First Noted and Occurrence, or a description of the AE.
- The greatest disparity in response rates occurred for Question Date (30.4% higher by HCPC, followed by Lot Number (26.7% higher by HCPC and Product Start Date (21.5% higher by consumers).

Results continued

- Amongst reports earning a score of 4, the lowest response rates were to questions regarding Outcome of Event and Product End Date (Figure 4).
- One large portion of reporters are not knowledgeable of enough details or are unwilling to provide a complete report.
- Amongst knowledgeable and willing reporters, the quality of report is high and contains approximately 75% of elicited information. A higher quality report suggests reporters are receptive to additional questions in support of more comprehensive reporting.
- On average, the quality of report does not differ between consumers and HCPs.
- HCPs are more likely to provide the lot number and expiration date.
- Consumers are more likely to provide a defined outcome for the AE and the due date the product was started.
- Further research is needed to understand why a large portion of reporters are unable or unwilling to provide a complete report.

Limitations

The generalizability of the results may be limited by the overall low rate of completeness amongst all reports. Factors include the reporter's knowledge of the event, willingness to report details, and the accuracy of documentation by the medical information specialist.

Conclusions

- There is a severe lack of understanding regarding the evaluation of AE reports received through the MICC channel.
- A large portion of reporters are not knowledgeable of enough details or are unwilling to provide a complete report.
- Amongst knowledgeable and willing reporters, the quality of report is high and contains approximately 75% of elicited information. A higher quality report suggests reporters are receptive to additional questions in support of more comprehensive reporting.
- On average, the quality of report does not differ between consumers and HCPs.
- HCPs are more likely to provide the lot number and expiration date.
- Consumers are more likely to provide a defined outcome for the AE and the due date the product was started.
- Further research is needed to understand why a large portion of reporters are unable or unwilling to provide a complete report.

References


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