Monitoring device performance after a product has been launched is a critical aspect of maintaining product safety. Not only is it the right thing to do, but our regulators expect that it’s done.

- FDA 21 CFR 822 discusses monitoring and evaluation of product performance data.
- The medical device risk management standard ISO 14971 requires that manufacturers establish, document, and maintain a system to collect post-production quality information and act on that information.
- MEDDEV 2.12-1 specifically discusses the guideline that product incidents shall be monitored against established trigger levels based on risk documentation, and expects a manufacturer to submit a report to the competent authorities when those expected thresholds are exceeded.

A good postmarket surveillance system can inform a company of emerging issues before they lead to patient harm, or even prevent exposure of potentially brand-damaging problems.

In an effort to benchmark practices at several medical device companies, a survey was sent out in September 2013 asking questions regarding their systems to monitor and act upon postmarket data. This article summarizes those findings.

The Survey
The Midwest Complaint Discussion Group is group of healthcare product manufacturers with offices located in the Midwest. A short survey was sent out to members of this peer-learning group. The questions were:
1. What is the typical level of attendance/titles for product monitoring meetings?
2. What extent or type of documentation is completed to provide objective evidence of the product monitoring meetings (discussion, decisions, action items, and outputs)?
3. What is the frequency of the product monitoring that occurs, and how often is a quorum held to discuss issues, or make decisions on product actions?
4. Who owns the decision-making process for taking action?
5. Are there veto options by any functional group?
6. Can you describe your data sources (complaints, MDRs, etc.), data analysis methods (statistical, triggers, normalization, etc.), and the analysis tools you use (off-the-shelf tool, Access, Excel, SQL, etc.)?
7. Is the product monitoring process standardized across all product lines or types, or does each group customize its analysis for its products?
8. What do you feel is good about your
current processes for monitoring product performance in the field?

9. What have you seen and WOULDN'T DO AGAIN with respect to postmarket product analysis?

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Feedback Received

The questions were intentionally open-ended to get a deeper understanding of different company's approaches to postmarket surveillance. The following feedback is an amalgamation of multiple responses.

What a PMS system is supposed to do:

Start with the end in mind—what are you trying to get out of the data, and what do you need to see? Optimally, a PMS should tell you if there’s a problem with the product, or indicate if there's a shift in predicted or expected rates of occurrence to prevent a problem of your product. Additionally, measurement systems continuously need to be evaluated to determine if you are looking at the data “right,” not just looking at the “right” data. Any measurement or metric should be assessed against the SMART method—specific, measurable, actionable, relevant, and timely. If you are gathering data for any metric that doesn’t meet these criteria, you should ask yourself whether it’s something that is valuable to gather and consider discontinuing the data collection.

What a PMS system can include:

The primary source of data for PMS is customer-received complaints (inclusive of any regulatory feedback or medical device reporting/field alert report/adverse event data). This is an important feeder source and a direct piece of feedback about the customer experience, but it’s also a lagging indicator of a customer issue. Other sources that can help bring a more predictive and holistic perspective to your listening systems is to include internally identified issues, materials/supplier/purchasing controls, service/installation data, manufacturing data, field safety correction action, publications, or newsletters. If you are able to monitor all of these pieces of the puzzle using similar root causes, or coding groupings, then the system can be aggregated and evaluated for issues that are escalating BEFORE they get into customer hands.

What to consider—Parameters for measurement systems:

Every company, even possibly every product, has its own special needs, as do all organizations with respect to the expectations on what should be reviewed and how. Using good statistical analysis methods/tools is an ongoing process that may be continuously shifting based on the lifecycle status and product usage characteristics. Typically, there are four main elements to consider when looking at data:

1. Risk thresholds (risk file or equivalent based predicted or documented limits, established “alert limits” as early warning indicator)
2. Normalization factors (sales, population, installed base, or no normalization-count)
3. Type of analysis (trend charting, Pareto analysis, change point analysis, t-Tests, etc.)
4. Frequency of analysis (quarterly, monthly, weekly, daily, live—dependent on risk, and need for monitoring)

Processes, Authority, And Documentation

Survey results indicated an overwhelming agreement that across a company, for a specific product type, consistency and standardization of methods and processes is optimal because you are then able to monitor apples to apples, so to speak, and roll data up through the company across multiple product lines to watch for emerging issues. Several respondents indicated that having a single group produce these data for all product lines was also a valuable asset to the PMS system as well. This is not to say that a specific plant or product group may want to monitor more than the minimum or standard set of metrics, there may be a very valid reason for doing so. In this case, you want to be sure that the raw data are made available to all locations so that they can use the data accordingly.

For any PMS system, it’s important to have

Optimally, a postmarket surveillance (PMS) system should tell you if there’s a problem with the product or indicate if there’s a shift in predicted or expected rates of occurrence to prevent a problem of your product.

Using good statistical analysis methods/tools is an ongoing process that may be continuously shifting based on the lifecycle status and product usage characteristics.
A company needs to establish the right measurements and triggers for your product and systems, have those systems proceduralized, and create documentation that proves that you are meeting those requirements.

Respondent Definitions of Quality:

- Don’t overdo the analysis activities—monitor logical, action driven minimum metrics (Use SMART).
- Utilize a risk-based approach for products as a starting point; at some junction a buffer may be used as an alert threshold to start proactively address issues.
- Complaint trending reviews need to happen regularly and be reviewed by crossfunctional teams. Reviews and decisions are documented.
- Trend complaints by product family or logical groupings where appropriate.
- Trend total complaints and root causes.
- Require documented investigations of all observed trends.
- Communicate or disseminate information for product awareness that is understandable for all employees.
- Use analysis tools that aggregate and analyze like data in a holistic manner.

Respondent Input on Factors to Avoid:

- Trending on complaint data tends to primarily focus on hazardous complaints versus our prediction on frequency of occurrence and may not effectively consider product quality issues that could require actions.
- Data analysis and processes for creating the routine PMS data that are overly cumbersome or complicated
- Don’t make assumptions that a new product will behave in a similar way to anything you’ve seen before.
- Refrain from initiating actions on data that has not exceeded a threshold; focus on those items first and foremost for action.
- Tools that drive the processes and analysis methods

Conclusion

There are many ways to manage and optimize a PMS system; there are a number of parameters, methods, tools and systems to consider. A company needs to establish the right measurements and triggers for your product and systems, have those systems proceduralized, and create documentation that proves that you are meeting those requirements. As respondents pointed out, adding more of the wrong kind of data is not better than starting with the right data to begin with. Ultimately, a good PMS system allows us to ensure that we have the needed visibility of arising issues—in a predictive and holistic manner—so that we can guarantee the safety of our users and patients.

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