MDRs and Registries

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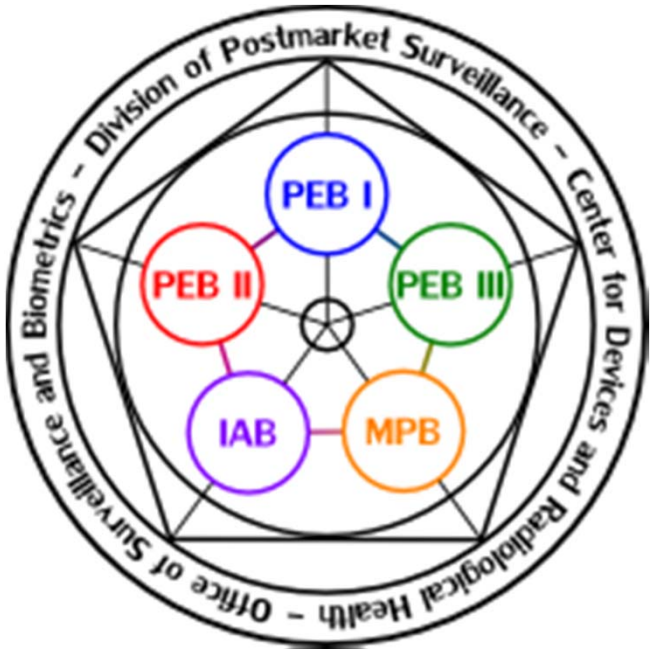

Topics

I. Background on MDR Reporting

II. Complimentary Picture – MDRs and Registry Data

III. General Considerations for Reporting of MDRs from Registry Data

Background: What does DPS do?

Purpose:

- To conduct global post-market surveillance of medical devices and related emerging technologies through the regulation, collection, integration, and dissemination of adverse event data to identify and communicate actual and/or potential public health risks to FDA and public stakeholders.

How we achieve our goal:

- Establish, interpret, and enforce requirements for medical device reporting (21 CFR Part 803- Medical Device Reporting); and provide outreach and education to FDA and public stakeholders to help them understand the requirements of the medical device reporting regulation.
- Monitor, analyze and synthesize adverse event data to identify signals (of new device issues) and trends (of known device issues); and to ensure that CDRH effectively uses adverse event report data in premarket review, postmarket evaluation studies, compliance and enforcement matters, and timely public health communications in support of the CDRH mission.
- Lead the continuous refinement and maintenance of the IT postmarket infrastructure to efficiently receive, process, retrieve, and analyze adverse event data in support of CDRH and FDA offices.

Medical Device Reporting Regulation

Medical Device Reporting (MDR, 21 CFR Part 803)

- Establishes the reporting requirements for device user facilities, manufacturers and importers.
- A mechanism for FDA and manufacturers to identify and monitor significant adverse events involving marketed medical devices.

What Types of Events Must Be Reported to FDA?

- If device may have **caused or contributed** to a death or serious injury.
- Certain malfunctions must also be reported.

Additional requirements:

- All information required on the FDA Form 3500A
- Develop and implement written MDR Procedures (21 CFR Part 803.17)
- Establish and maintain MDR event files (21 CFR Part 803.18)
- Device manufacturers must conduct a **complete investigation** of each event (as per 21 CFR Part 820.198)

Medical Device Reporting Requirements

REPORTER	WHAT TO REPORT	WHERE	WHEN
Manufacturer (Mfr) (Domestic and Foreign)	Deaths, Serious Injuries, Malfunctions	FDA	Within 30 calendar days of becoming aware
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 working days of becoming aware
User Facility	Deaths	FDA and Mfr	Within 10 working days
	Serious Injuries	Mfr (FDA if unknown)	Within 10 working days
Importer	Deaths and Serious Injuries	FDA and Mfr	Within 30 calendar days
	Malfunctions	Mfr	Within 30 calendar days
Voluntary	Any type of event	FDA	Any time

Best Use of MDRs…

- **Qualitative profile of adverse events for a device or device type**
  - Device use in real world
  - Types of malfunctions/clinical events
  - Subgroup profiles

  } How manufacturers are addressing issues

- **Monitor device performance**
  - Time to event and failure modes
  - New types of issues with approved devices
  - Monitoring long term device use
  - Effectiveness of manufacturer corrective actions

- **Signal detection**
  - Rare, serious, or unexpected events
  - Change in severity of expected events
  - Use error/human factors issues

Reviewing MDRs…

- **Analysts consider multiple factors**
  - Natural history of the underlying disease/disorder
  - Underlying comorbidities
  - Concomitant medication or therapies
  - Concomitant surgical procedures

- **Monitor trends – temporal analysis of MDRs for particular products**
  - Market share of one product versus other
  - Recent manufacturer inspection
  - Recent recall
  - Recent media attention
  - Reporting habits of one company over another

- **Supplemental information**
  - MDR Database Searches
  - Premarket information
  - Literature Review
  - -- Web Searches
  - -- Relevant Compliance Actions
  - -- Additional Information Requests

Limitations of MDR Data

- **Under-reporting**
  - Users unfamiliar with reporting or fear of unintended consequences if they report
  - Confusion about HIPAA privacy and reporting
  - Malfunction or injury may not be clinically apparent

- **Limitations of MDR regulation**: Certain device malfunctions may not meet MDR reporting requirements

- **Insufficient/Inadequate information in report**
  - Information not obtainable from end user
  - Devices not returned or made available for manufacturer evaluation

- **Inability to definitively establish causality**
  - Cannot definitively determine link/causality between the use/malfunction of the device and the negative clinical adverse event or outcome in that report.

Complimentary Picture: MDRs and Registry Data

Complimentary - MDR and Registries

- Registries provide a robust estimation of incidence rate of adverse events of known clinical outcomes that cannot be gleaned from MDR data.
- MDRs provides an understanding of device malfunctions, emergent clinical events, and “out-of-the-box” failures of medical devices not captured in registries.
- Registries robustly capture device experience from user facilities.
- MDRs effectively capture results of manufacturer investigation and what approaches are used to correct device issues.
- Registries are effective at monitoring clinical outcome.
- MDRs are effective at monitoring effectiveness of recalls and device enhancements.

General Considerations for Reporting of MDRs from Registry Data

Considerations for Manufacturers in Reporting of MDRs from Registry Data

- For each quarter, a manufacturer submits one summary MDR that summarizes what reports they have received from the registry. This MDR should contain a narrative summary that:
  - Notes the nature, number and rate of product problems/adverse events that are captured by the registry for that quarter
  - Describes what investigation steps and corrective actions the manufacturer has taken to address any issues described in the summary report

Streamlines data collection.

- Device-related death or serious injury events that are not captured by the registry's case report form are submitted as MDRs. Malfunction reports and reportable death or serious injury events that are related to a device malfunction should be reported as MDRs.

Anything not captured by registry should be in MDRs.

Considerations for Manufacturers in Reporting of MDRs from Registry Data

- Events of imminent threat or adverse events that require a 5-day MDR submission should be reported as MDRs.

  Immediate public health risks are excluded.

- Manufacturers who are currently engaged in a remedial action or a recall, or any other 806-related issue are required to submit MDRs related to those events.

  Regulatory related issues are excluded.

- Manufacturers who receive data from a registry may not report this information as part of an ASR quarterly submission. If an existing exemption is in place for adverse events that are collected by a registry – the exemption should be discontinued.

  No duplicative summary reporting mechanisms.

Considerations for Registries to Facilitate Better Manufacturer Reporting of MDRs

- Data should be available from the registry on a regular timely basis that is at least once every 90 days. An update schedule and history log should be posted so that this information is available to the manufacturer and FDA.

  Registry data availability must be timely and predictable.

- The registry should refer reporters to the FDA MDR website for any device-related death or serious injury adverse events that are not specifically captured by the registry case report forms.

  FDA website for reporting adverse events not collected in registry.

- The registry should not incorporate an "other: narrative field to capture miscellaneous device-related events. If they are not classified as a structured data element in the registry, then user facilities should be reminded to report this information as MDRs (if mandated) and encouraged to report (if not mandated, e.g. out-of-box failures)

  No generic "Other" bucket… file as MDRs.

Closing Thought…

Both registries and MDRs data sources have their strengths, but can be used together to provide a more complete understanding of medical device performance.