

# Survey of Current Practices Regarding Notification and Management of Healthcare Product Alerts

Patient safety and medical errors are critical issues in healthcare today. In addition to developing strategies to reduce incidents within their facilities, healthcare organizations need better ways to obtain and respond to external information about potential hazards and safety concerns. Each year, health care organizations receive-either directly or through third parties-numerous product and safety alerts.

Noblis developed this survey to capture information on your current practices in acquiring, processing, and managing alerts. The survey should take 15 to 20 minutes to complete.

## I. Healthcare Organization

**Q1 Which of the following most accurately describes your healthcare organization**

*Hospital*

*Health System*

*Ancillary Facilities and Clinics*

Hospital (An independent hospital providing inpatient medical care which may have associated ancillary facilities and/or clinics providing ambulatory medical care)

Health System (One or more affiliated hospitals providing inpatient medical care which may have associated ancillary facilities and/or clinics providing ambulatory medical care)

Ancillary Facilities and Clinics (One or more affiliated facilities providing ambulatory medical care such as outpatient surgical centers, independent lab or blood banks, urgent care centers, or radiology centers)

Please tell us about yourself and your organization.

**Q2 Please indicate the name of your organization:**

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**Q3 Please provide your name:**

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**Q4 Please provide your role in the organization:**

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**Q5 Please provide your telephone number:**

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**Q6** Please provide your email address:

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**Q7** Please indicate the number of facilities of each type within your organization.

Hospitals	_____
Clinics	_____
Physician Practices	_____
Ancillary Facilities	_____
Psychiatric Facilities	_____
Long-term Care Facilities	_____
Other Types of Facilities	_____

**Q8** What is the size of your health care organization in licensed beds?

- < 100
- 101 - 300
- 301 - 500
- 501 - 700
- 701 - 900
- 901 - 1500
- 1501 - 2000
- > 2000

**Q9** What is the number of visits per year in the ancillary facilities and clinics?

- < 50,000
- 50,001 - 100,000
- 100,001 - 150,000
- 150,001 - 200,000
- 200,001 - 250,000
- 250,001 - 300,000
- 300,001 - 350,000
- 350,001 - 400,000
- > 400,000

## II. Alert Management Process

**Q10** Please describe your current alert management process:

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**Q11 Please identify the most significant problems with your current alert management process:**

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**Q12 What are your goals for an improved alert management process?**

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**Q13 Do you have a documented alert management policy for your organization?**

- Yes, across all facilities and departments*
- Yes, for some facilities and departments*
- No*
- Don't know*

**Q14 Do you have guidelines for the acceptable time to process alerts?**

- Yes, across all facilities and departments*
- Yes, for some facilities and departments*
- No*
- Don't know*

**Q15 Do you currently have a tracking system in place for managing alerts?**

- Yes, an automated tracking system or service*
- Yes, a basic automated tracking system (e.g., a spreadsheet or database)*
- Yes, a manual tracking mechanism*
- No*
- Don't know*

**Q16 How easy is it to retrieve the record of actions performed in addressing an alert?**

- Very easy*
- Somewhat easy*
- Somewhat difficult*
- Very difficult*
- Don't know*

**Q17 Are alerts centrally managed or handled by individual departments?**

- Centrally managed for all facilities*
- Centrally managed at each facility*
- Distributed to individual departments*
- Other (please specify)*



- Q18 Do you have a defined organizational structure and responsibilities for handling alerts?**  
*Yes, well defined*  
*Yes, informally defined*  
*No*  
*Don't know*  
*Other (please specify)*
- Q19 Does the staff responsible for coordinating alerts need to review notices for multiple departments or just the departments for which they are responsible?**  
*Staff review notices for multiple departments*  
*Staff review notices only for responsible departments*  
*Don't know*
- Q20 Which departments in your organization are responsible for managing alerts?**  
*Risk Management*  
*Materials Management*  
*Purchasing*  
*Quality*  
*Nursing*  
*Laboratory*  
*Pharmacy*  
*Other (please specify)*
- Q21 Does management have the means to monitor on-going alert processing activities?**  
*Yes, across all facilities and departments*  
*Yes, at some facilities and departments*  
*No*  
*Don't know*
- Q22 Does management have the means to know when action on an alert is delayed?**  
*Yes, across all facilities and departments*  
*Yes, for some facilities and departments*  
*No*  
*Don't know*
- Q23 Do you have a process for dealing with poorly performing alert processing team members?**  
*Yes, across all facilities and departments*  
*Yes, at some facilities and departments*  
*No*  
*Don't know*

- Q24 Can management obtain historical reports of alert processing activities (e.g., volume of alerts and processing times by department or facility)?**  
*Yes, across all facilities and departments*  
*Yes, at some facilities and departments*  
*No*  
*Don't know*
- Q25 Does your process have any provisions for addressing urgent alerts?**  
*Yes*  
*No*  
*Don't know*
- Q26 Does your process have any provisions for addressing the clinical impact of alerts (e.g., contacting relevant physicians and patients)?**  
*Yes*  
*No*  
*Don't know*
- Q27 Does your process have any provisions for involving senior leadership with critical high-visibility alerts?**  
*Yes*  
*No*  
*Don't know*

### III. Alert Acquisition

- Q28 What are your major sources of healthcare product alerts?**  
*Product Vendor Notices*  
*FDA MedWatch*  
*FDA Enforcement Report*  
*ECRI*  
*NRAC*  
*MedSun*  
*MDBuyline*  
*Internet or listservs*  
*Others (please specify) \_\_\_\_\_*

**Q29 For which of the following departments do you currently receive alerts?**

Yes No Don't know

Biologics  
Biomedical Devices  
Blood Products  
Children's Consumer Products  
Engineering and Facilities  
Food  
Information Systems  
Laboratory Products  
Medical Supplies  
OR Products  
Other Products  
Pharmaceutical Products  
Radiology Products  
Tissue

**Q30 On average, how many alerts do you receive in a week across all the departments?**

**Q31 Do you have a means for identifying duplicate product alerts which you have already received?**

Yes  
No  
Don't know

**Q32 Indicate the current mechanisms by which you obtain alerts from external sources.**

Yes No Don't know

Mail  
E-Mail  
Fax  
Internal Routing  
Web  
Other

**Q33 Indicate the current mechanisms by which you distribute alerts within your organization.**

Yes No Don't know

Mail  
E-Mail  
Fax  
Internal Routing  
Web  
Phone  
Other

## IV. Alert Processing Times

- Q34** How long does it usually take you to obtain alerts from the date of their publication by your alert sources? (Note that "days" in this survey refer to business days (Monday through Friday) and not calendar days.)
- Within 1 day*
  - Within 1 - 2 days*
  - Within 3 - 5 days*
  - Within 6 - 10 days*
  - Greater than 10 days*
  - Unknown*
- Q35** How long does it usually take for alerts to reach your facility's staff who are responsible for disposing of products from the date you initially obtain them?
- Within 1 day*
  - Within 1 - 2 days*
  - Within 3 - 5 days*
  - Within 6 - 10 days*
  - Greater than 10 days*
  - Unknown*
- Q36** How long does it usually take to complete action on alerts from the date the alerts are distributed to the staff responsible for disposing of products?
- Within 1 day*
  - Within 1 - 2 days*
  - Within 3 - 5 days*
  - Within 6 - 10 days*
  - Greater than 10 days*
  - Unknown*
- Q37** How long does it usually take to complete the documentation on alerts from the date the action has been completed on the product?
- Within 1 day*
  - Within 1 - 2 days*
  - Within 3 - 5 days*
  - Within 6 - 10 days*
  - Greater than 10 days*
  - Unknown*
- Q38** If you are unable to answer the previous four questions, please estimate the total time your organization takes from the date of alert publication to complete and document your actions.
- Within 3 - 5 days*
  - Within 6 - 8 days*
  - Within 9 - 12 days*
  - Within 13 - 16 days*
  - Within 17 - 20 days*
  - Greater than 20 days*
  - Unknown*

## V. Alert Processing Costs

If you are a current RASMAS subscriber, please skip questions 39 through 42.

**Q39** How many staff-hours per week are spent on identifying and researching alerts at a facility?

- 0
- 1-2
- 3-5
- 6-10
- 11-15
- > 15
- Unknown

**Q40** How many staff-hours per week are spent on managing and coordinating responses to alerts at a facility?

- 0
- 1-2
- 3-5
- 6-10
- 11-15
- > 15
- Unknown

**Q41** How many staff-hours per week are spent disposing or returning products in response to alerts at a facility?

- 0
- 1-2
- 3-5
- 6-10
- 11-15
- > 15
- Unknown

**Q42** How many staff-days per year are spent researching actions on previous alerts at a facility in response to internal and external requests?

- 0
- Less than 1 staff-day
- Within 1 to 2 staff-days
- Within 3 to 4 staff-days
- Within 5 to 6 staff days
- Greater than 6 staff-days
- Unknown

## VI. Product Returns

- Q43** How many recalls have resulted in reimbursement for or replacement of defective products?
- None*
  - A few*
  - About one half*
  - Most*
  - Don't know*
- Q44** Please estimate the annual dollar value of manufacturer reimbursements for returned products. (Dollar value includes payments, credits, and replacement in kind.)
- None*
  - Less than \$100,000*
  - \$100,000 - \$250,000*
  - \$250,000 - \$500,000*
  - \$500,000 - \$1,000,000*
  - Greater than \$1,000,000*
  - Don't know*
- Q45** How well are you able to track reimbursements for returned products?
- Unable to track*
  - Minimally*
  - Adequately*
  - Effectively*
  - Don't know*
- Q46** Do you bill manufacturers for your costs, direct and indirect, associated with recalled products?
- No*
  - In some cases*
  - Whenever possible*
  - Don't know*

Thank you for completing our survey and helping us to understand your current practices in the handling of healthcare product alerts.