

Results of the SMI Provider Survey on Product Recalls

September 2009

- 1 AHRMM announced the SMI survey via a story and link in the **AHRMM eNews** on August 25 and September 1, 2009.
32 entries were received.



5. Provider Survey on Product Recalls

The Strategic Marketplace Initiative (SMI), a non-profit industry organization dedicated to advancing the healthcare supply chain industry and a collaborator with AHRMM, is sponsoring an [industry survey](#) to foster greater understanding of the Provider's approach and challenges to managing product recalls. Your participation in this [voluntary survey](#) will support the work of an SMI Team focused on the industry's overall challenges with the recall process. The survey will be anonymous and requires just three to five minutes to complete. In addition to completing the survey, provider-based professionals are free to contribute their comments, recommendations, and best practice information on product recalls via email to SMI's Dennis Orthman at dorthman@smisupplychain.com. In the months ahead, SMI will make the results of this Provider survey public via its web site www.smisupplychain.com.

- 2 SMI redistributed the survey via email to SMI Provider members on September 15, 2009.
15 additional entries were received.

47 Total Provider Responses Recorded

Questions 1 and 2

Question 1

SMI's Product Recall Survey For Providers 2009

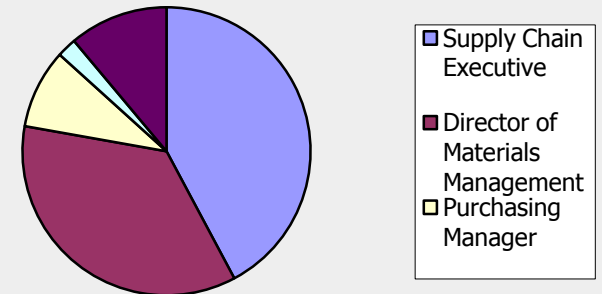
Please indicate your organization type.		
Answer Options	Response Percent	Response Count
Patient Care Provider Organization (Hospital, healthcare	100.0%	45
Other (please specify)	0.0%	0
answered question		45
skipped question		2

100% of responses were from Providers

Question 2

Please indicate your current position.		
Answer Options	Response Percent	Response Count
Supply Chain Executive	42.2%	19
Director of Materials Management	35.6%	16
Purchasing Manager	8.9%	4
Supply Chain Staff	2.2%	1
Other (please specify)	11.1%	5
answered question		45
skipped question		2

Please indicate your current position.

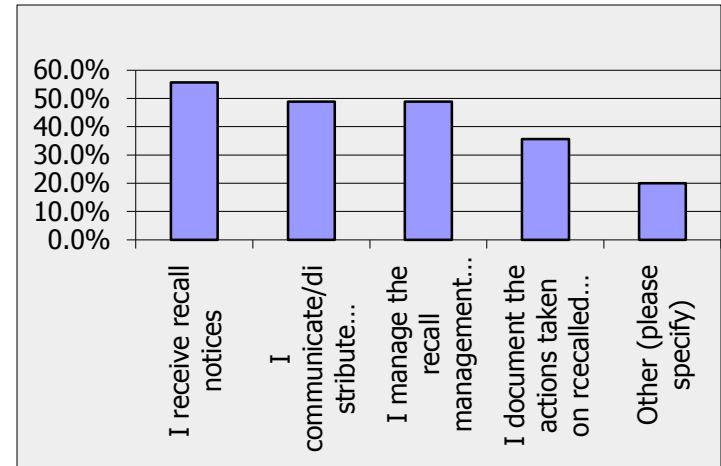


Questions 3 and 4

Question 3

What is your degree of involvement in your organization's product recall management program? (check all that apply)

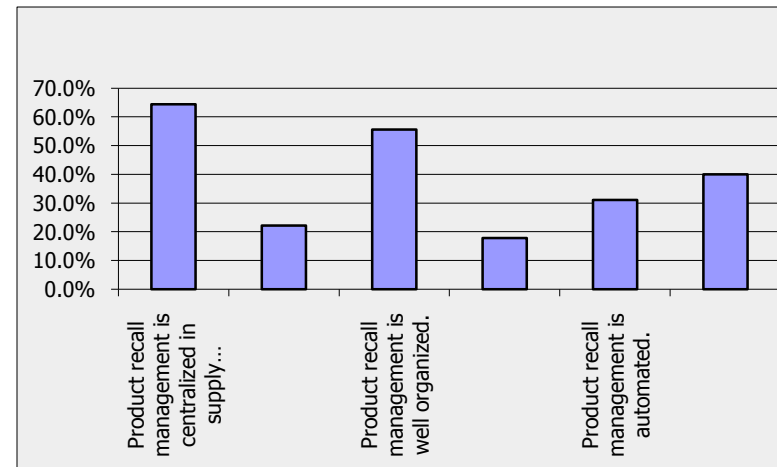
Answer Options	Response Percent	Response Count
I receive recall notices	55.6%	25
I communicate/distribute internally about recall notices	48.9%	22
I manage the recall management process	48.9%	22
I document the actions taken on rcalled products	35.6%	16
Other (please specify)	20.0%	9
answered question		45
skipped question		2



Question 4

Please select the description below that best describes your organization's overall program for product recall management.(check all that apply):

Answer Options	Response Percent	Response Count
Product recall management is centralized in supply	64.4%	29
Product recall management is de-centralized and	22.2%	10
Product recall management is well organized.	55.6%	25
Product recall management is not well organized.	17.8%	8
Product recall management is automated.	31.1%	14
Product recall management is not automated.	40.0%	18
answered question		45
skipped question		2

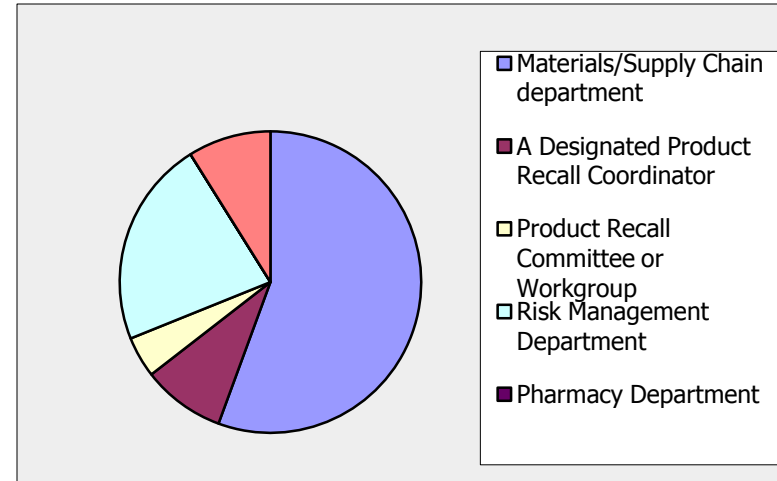


Questions 5 and 6

Question 5

Which person, department, or group has the primary responsibility for product recall management within your organization?

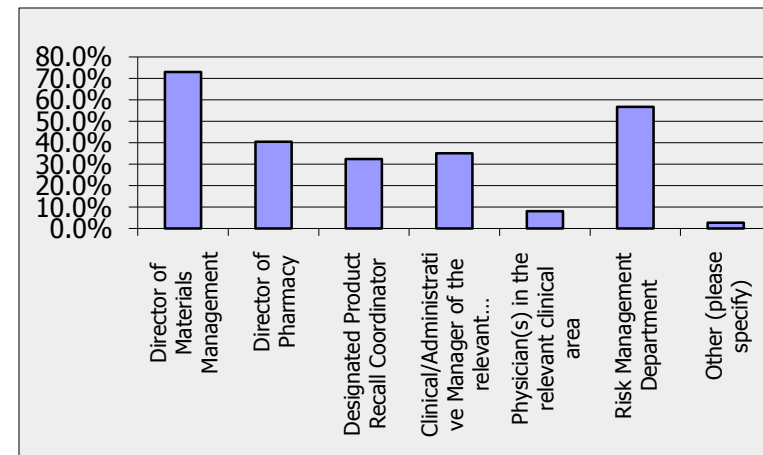
Answer Options	Response Percent	Response Count
Materials/Supply Chain department	55.6%	25
A Designated Product Recall Coordinator	8.9%	4
Product Recall Committee or Workgroup	4.4%	2
Risk Management Department	22.2%	10
Pharmacy Department	0.0%	0
Other (please specify)	8.9%	4
answered question		45
skipped question		2



Question 6

Who in your organization typically is first to receive the product recall notifications? Check all that apply.

Answer Options	Response Percent	Response Count
Director of Materials Management	73.0%	27
Director of Pharmacy	40.5%	15
Designated Product Recall Coordinator	32.4%	12
Clinical/Administrative Manager of the relevant...	35.1%	13
Physician(s) in the relevant clinical area	8.1%	3
Risk Management Department	56.8%	21
Other (please specify)	2.7%	1
answered question		37
skipped question		10

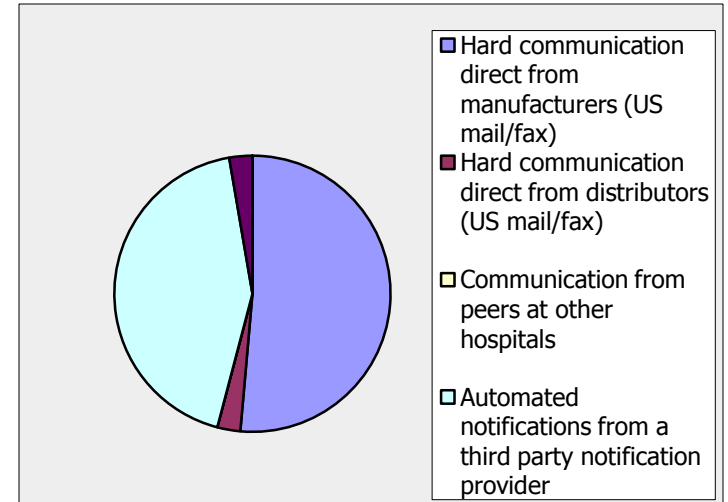


Questions 7 and 8

Question 7

What is your organization's primary method of receiving product recall notifications?

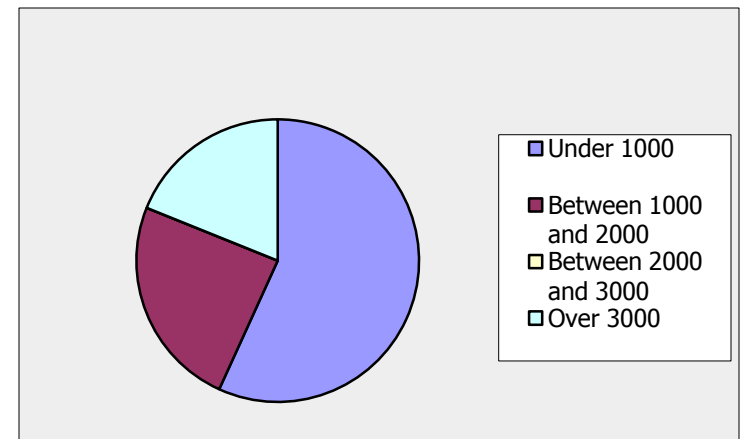
Answer Options	Response Percent	Response Count
Hard communication direct from manufacturers (US)	51.4%	19
Hard communication direct from distributors (US)	2.7%	1
Communication from peers at other hospitals	0.0%	0
Automated notifications from a third party notification	43.2%	16
Web site monitoring and surveillance	2.7%	1
Other (please specify)	0.0%	0
answered question		37
skipped question		10



Question 8

Approximately how many product recall notifications does your organization receive on an annual basis?

Answer Options	Response Percent	Response Count
Under 1000	56.8%	21
Between 1000 and 2000	24.3%	9
Between 2000 and 3000	0.0%	0
Over 3000	18.9%	7
answered question		37
skipped question		10

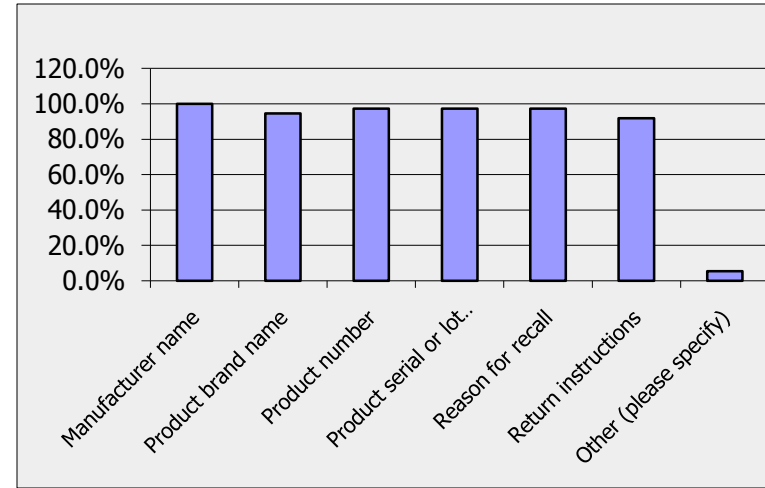


Question 9 and 10

Question 9

**What information does your organization typically receive on a recall notice?
Please check all that apply:**

Answer Options	Response Percent	Response Count
Manufacturer name	100.0%	37
Product brand name	94.6%	35
Product number	97.3%	36
Product serial or lot number	97.3%	36
Reason for recall	97.3%	36
Return instructions	91.9%	34
Other (please specify)	5.4%	2
answered question		37
skipped question		10



Question 10

Please describe information that is not typically provided that you would like to see included in product recall notices.

Answer Options	Response Count
	13
answered question	13
skipped question	34

Responses:

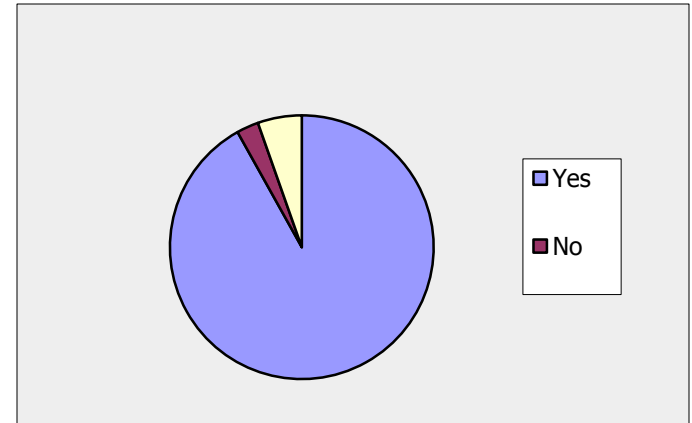
1. Return instructions
2. History of product ownership
3. An anecdotal report of incidents that triggered the recall.
4. Patient information
5. The purchase order that was used for the original purchase.
6. Purchase Order Number
7. What the product is used for. Which department uses the item.
8. issue is when the above information is not complete
9. Global Trade ID Numbers.
10. Qty & location of shipments to my organization.
11. You usually have to let them know that you have some defective product and then wait for the RGA. It would be nice if they gave you the RGA with the recall information.
12. purchase order history

Questions 11 and 12

Question 11

Does your organization have documented policies and procedures for the recall management process?

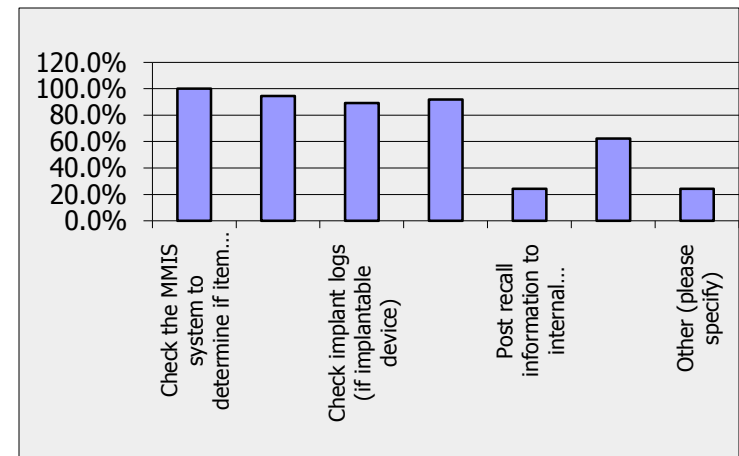
Answer Options	Response Percent	Response Count
Yes	91.9%	34
No	2.7%	1
Don't Know	5.4%	2
answered question		37
skipped question		10



Question 12

Once notified, what actions does your organization take to respond to the recall? (Check all that apply)

Answer Options	Response Percent	Response Count
Check the MMIS system to determine if item has ever been ordered	100.0%	37
Manually inspect inventory locations and gather product	94.6%	35
Check implant logs (if implantable device)	89.2%	33
Send electronic communication to affected department managers	91.9%	34
Post recall information to internal bulletins/web site	24.3%	9
Notify affected patients	62.2%	23
Other (please specify)	24.3%	9
answered question		37
skipped question		10

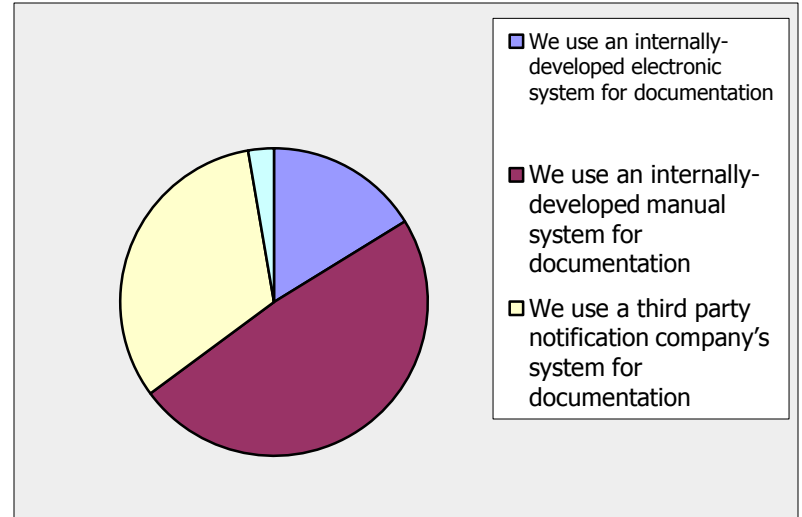


Questions 13 and 14

Question 13

How do you document what action has been taken on a recalled item?

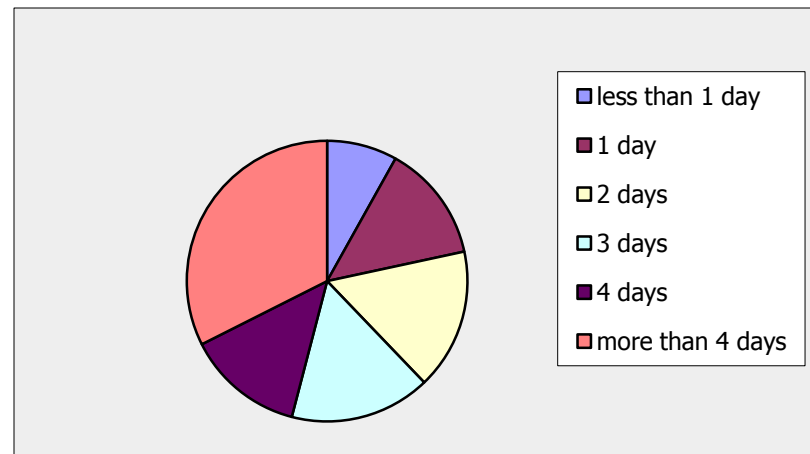
Answer Options	Response Percent	Response Count
We use an internally-developed electronic system for documentation	16.2%	6
We use an internally-developed manual system for documentation	48.6%	18
We use a third party notification company's system for documentation	32.4%	12
Other (please specify)	2.7%	1
answered question		37
skipped question		10



Question 14

Once notified of a product recall, how many days on average does it take for your organization to fully complete all the required actions in your product recall process?

Answer Options	Response Percent	Response Count
less than 1 day	8.1%	3
1 day	13.5%	5
2 days	16.2%	6
3 days	16.2%	6
4 days	13.5%	5
more than 4 days	32.4%	12
answered question		37
skipped question		10

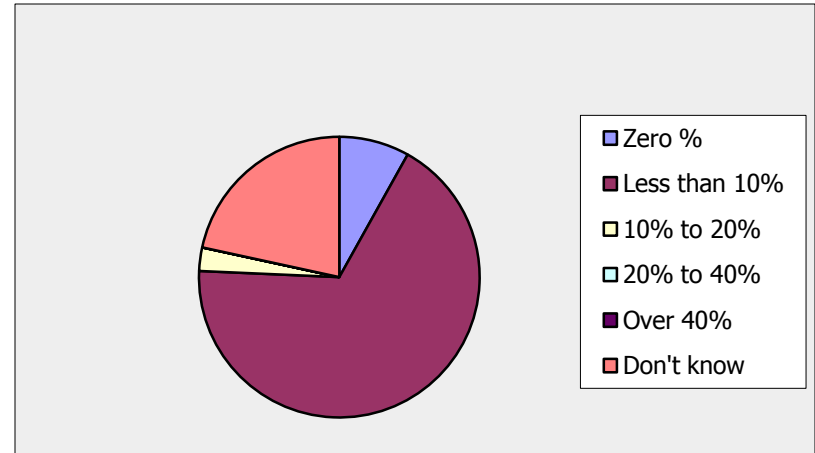


Questions 15 and 16

Question 15

Of all recall notices received, please estimate the percentage of recalls that require that a patient(s) be notified of a recalled item that may have been a part of their care?

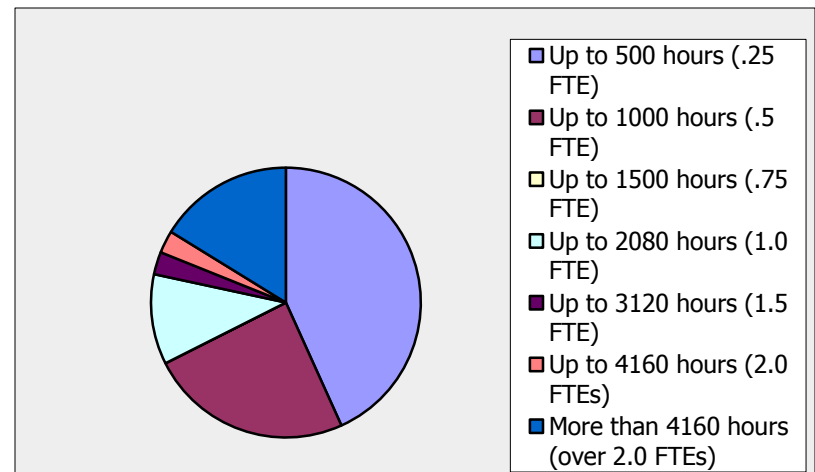
Answer Options	Response Percent	Response Count
Zero %	8.1%	3
Less than 10%	67.6%	25
10% to 20%	2.7%	1
20% to 40%	0.0%	0
Over 40%	0.0%	0
Don't know	21.6%	8
answered question		37
skipped question		10



Question 16

Please estimate the total number of paid hours of staff time required annually to properly manage your organization's recall program. Include all administrative, supply chain, risk management, clinical, and logistical staff.

Answer Options	Response Percent	Response Count
Up to 500 hours (.25 FTE)	43.2%	16
Up to 1000 hours (.5 FTE)	24.3%	9
Up to 1500 hours (.75 FTE)	0.0%	0
Up to 2080 hours (1.0 FTE)	10.8%	4
Up to 3120 hours (1.5 FTE)	2.7%	1
Up to 4160 hours (2.0 FTEs)	2.7%	1
More than 4160 hours (over 2.0 FTEs)	16.2%	6
answered question		37
skipped question		10

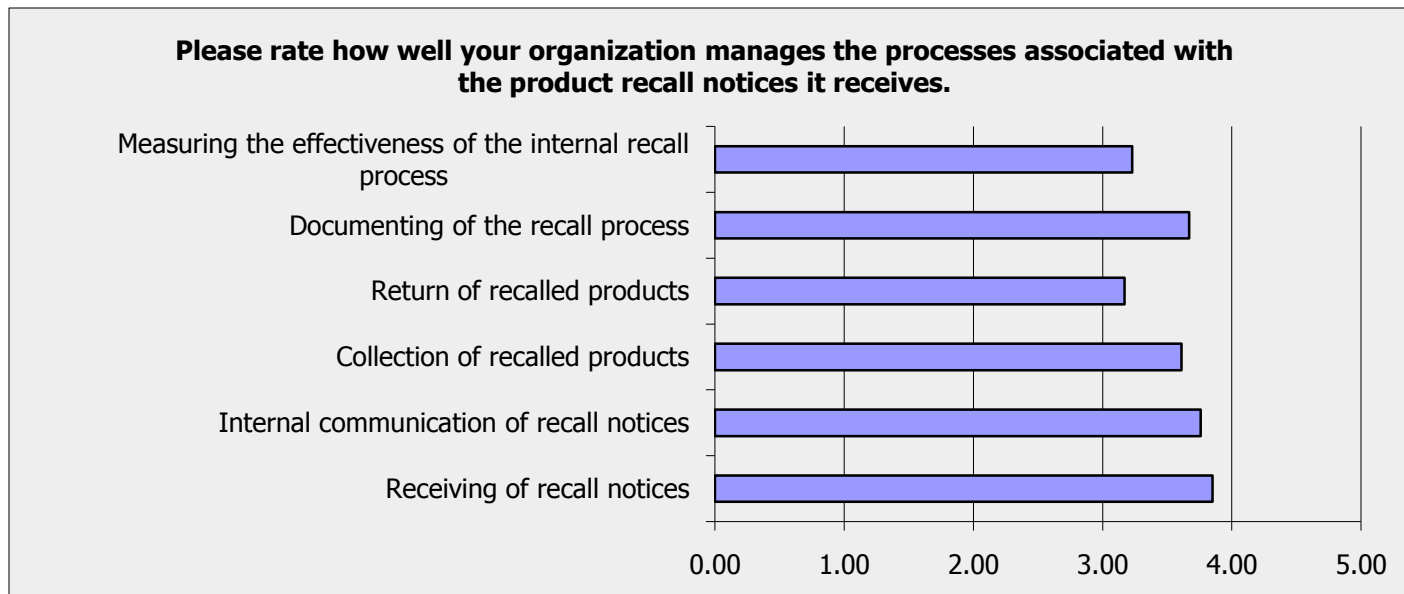


Question 17

Question 17

Please rate how well your organization manages the processes associated with the product recall notices it receives.

Answer Options	Poorly	Fair	Good	Very Good	Excellent	Not sure	Rating Average	Response Count
Receiving of recall notices	2	3	6	10	11	1	3.85	33
Internal communication of recall notices	1	3	5	8	8	0	3.76	25
Collection of recalled products	1	4	2	5	6	0	3.61	18
Return of recalled products	2	4	8	8	2	0	3.17	24
Documenting of the recall process	2	3	2	11	6	0	3.67	24
Measuring the effectiveness of the internal recall process	6	4	5	4	3	4	3.23	26
<i>answered question</i>								37
<i>skipped question</i>								10

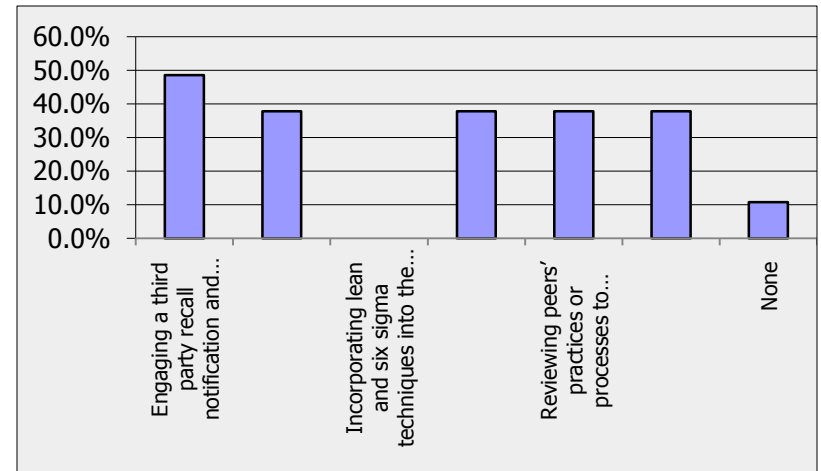


Questions 18 and 19

Question 18

In the last three years, what initiatives has your organization undertaken to improve the overall management of product recalls?
Check all that apply:

Answer Options	Response Percent	Response Count
Engaging a third party recall notification and management service	48.6%	18
A complete re-engineering of the current recall management process	37.8%	14
Incorporating lean and six sigma techniques into the recall process	0.0%	0
Conducting staff in-service training	37.8%	14
Reviewing peers' practices or processes to consider adopting	37.8%	14
Working with manufacturers or distributors to improve the communication flow	37.8%	14
None	10.8%	4
Comments		1
answered question		37
skipped question		10

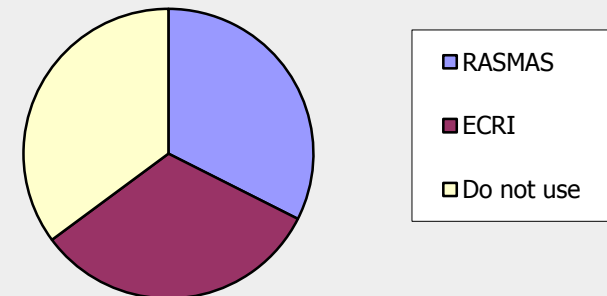


Question 19

If you use a third party product recall notification provider, please indicate the provider company.

Answer Options	Response Percent	Response Count
RASMAS	32.4%	12
ECRI	32.4%	12
Do not use	35.1%	13
Other 3rd party system (please specify)		2
answered question		37
skipped question		10

If you use a third party product recall notification provider, please indicate the provider company.



Questions 20 and 21

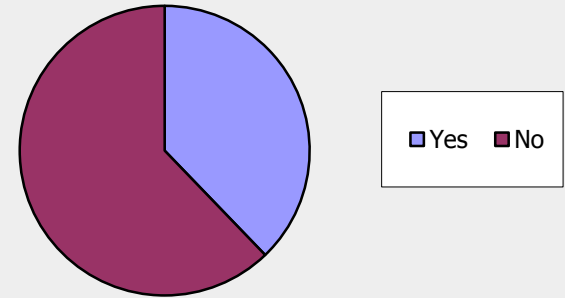
Question 20

Does your organization have metrics to measure the effectiveness of your product recall management program?

Answer Options	Response Percent	Response Count
Yes	37.8%	14
No	62.2%	23
If Yes, please specify the key metric		5
answered question		37
skipped question		10

1. Recalls closed with 20 days of notice
2. # of affected products/# of alerts
3. Average days to close
4. Monthly # of recalls – report to Safety Comm.

Does your organization have metrics to measure the effectiveness of your product recall management program?



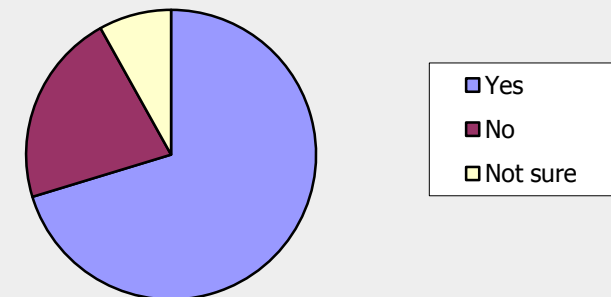
Question 21

Is product recall management a priority of your senior management and leadership?

Answer Options	Response Percent	Response Count
Yes	70.3%	26
No	21.6%	8
Not sure	8.1%	3
Comments		4
answered question		37
skipped question		10

1. Left to Dir. Of MM to manage completely
2. Class 1 recalls only to Sr. Mgt.
3. MD leadership and oversight
4. Running well. No need for Sr. Mgt.

Is product recall management a priority of your senior management and leadership?



Question 22

Question 22

What do you think are today's greatest challenges across the healthcare supply chain when managing the product recall process?

Answer Options	Response Count
	29
<i>answered question</i>	29
<i>skipped question</i>	18

1. Resources
2. Assuring recalled products are gathered and returned in a timely manner, particularly if in wide use.
3. Lack of pedigree information for commodities. Complexity of distribution. Complexity of production (outsourcing components). Lack of consistent standards for out-of-country production. Lack of adequate resources to monitor and manage compliance with production standards. Multiple methods of communication. Inconsistent regulatory reviewer interpretation of standards (TJC).
4. Obtaining data in a timely manner
5. Tracking the product at the Serial Number or lot number level is nearly impossible until it is implanted in a patient. Lot numbers require that we check every like product on the shelf.
6. Data standards for manufacturers.
7. Speed of getting the notice to the providers. Still comes as mail. Most request faxes in return, would prefer a PDF or other electronic file. The entire communication process could be completely electronic. Also the failure to include a PO number slows the process as the provider must search to find the purchase history of the item.
8. Recalls are impossible to manage without having a central repository for communicating all recalls and a standard format for disseminating the information.
9. Available time to respond to all recalls - the number is increasing all the time.
10. Getting the recall in a timely manner. they should all come to materials management but not all vendors send them there.

Question 22 (cont)

Question 22

What do you think are today's greatest challenges across the healthcare supply chain when managing the product recall process?

Answer Options	Response Count
	29
<i>answered question</i>	29
<i>skipped question</i>	18

11. Lack of automation to make all accountable for safety of patient.
12. Multiple notifications that keep coming even if you have responded to the original. This causes rework and confusion.
13. Getting the correct information in a timely manner
14. Rapid product identification; Traceability of the affected product to patients; the increasing tsunami of alerts/recalls.
15. The sheer volume of recalls, makes the process overwhelming!
16. If the recall does include an implant used on a patient this is the greatest challenge.
17. Supply Chain typically lacks the labor needed to manage this effectively - so it becomes a secondary function.
18. Information on equipment purchased by UHS
19. time in managing the process
20. Too many recalls are issued by manufacturers and the amount is increasing. This indicates that in general manufacturer quality control is ineffective and deteriorating.

Question 22 (cont)

Question 22

What do you think are today's greatest challenges across the healthcare supply chain when managing the product recall process?

Answer Options	Response Count
	29
<i>answered question</i>	29
<i>skipped question</i>	18

21. streamlining and making efficient.
22. The affected dept. is notified, acts on the recall in a timely manner, and communicates the results to those who need to know.
23. timely notification of product alerts and documenting the actions required to fully close the action required
24. notices not being sent to the correct person, number of multiple letters sent
25. Unquestionably: Systematically obtaining coherent input of information from manufacturers. They send recall notices to any of several titles: Director of Materials Mgmt., Risk Manager, CNO, CEO. In addition, some manufacturers are inept when it comes to getting a recall notice out to the hospitals. In one incident, it took about 90 days for a manufacturer to get the notice out the door. The letter was dated December 10; the UPS tracking information showed that the document did not leave the manufacturer until March 10. The recall involved a piece of physical therapy equipment with a software-based risk of electrical burn to the patient. Unfortunately, others are also slow - although not as slow as that manufacturer was.
26. Communication and cooperation w/ clinicians
27. Getting the notices to the correct individual in the hospital; often a sales rep will go directly to the user department and exchange the recalled product without following the proper notification and documentation
28. The increasing volume of recalls over the last two years
29. To many hands in the pot. Communication from manufacturer goes out to many people within an organization and they all do their own thing.

Question 23

Question 23

If you would like to share additional ideas, thoughts, or best practice information regarding product recall management and would like to be contacted by an SMI Recall Initiative Team member, please provide your contact information.

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