Patient Engagement Advisory Committee
FDA Medical Device Recalls
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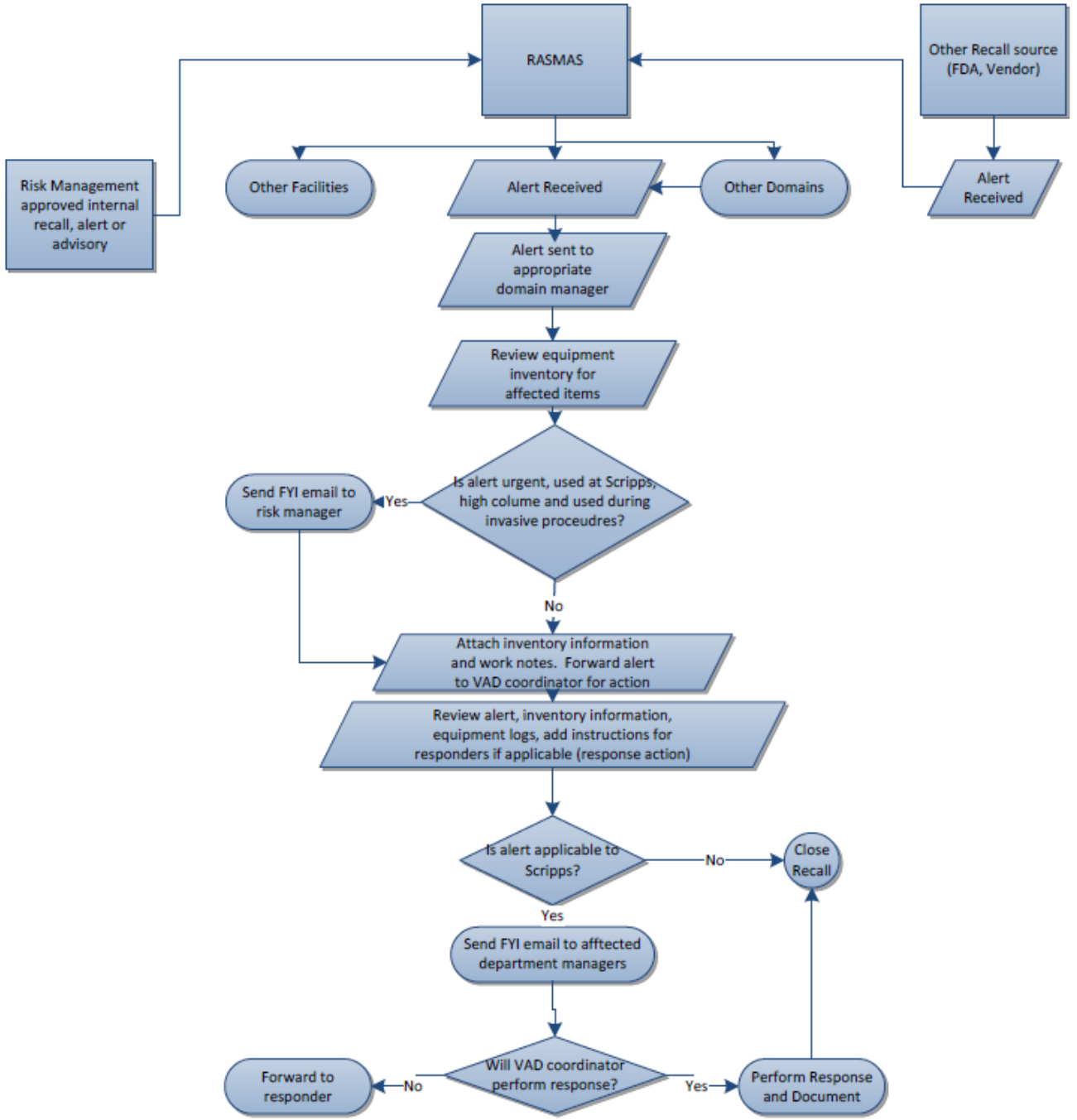
Clinically Integrated Supply Chain

- Centralized Supply Chain function
- Purchase ordering systems under one domain
- Full responsibility over Master Item File
- Nurses in Supply Chain creates clinical connection
- Rapid, coordinated response to recalls

Scripps

Recall notification from all directions

- Recall System Alerts
- Direct Alerts from Manufacturer
- Email Notification from REP
- Letter sent to BioMed, Supply Chain, Risk or Nursing Leadership
- Phone Call – Heads Up!


RASMAS
Other Recall source (FDA, Vendor)
Risk Management approved internal recall, alert or advisory
Other Facilities
Alert Received
Other Domains
Alert Received
Alert sent to appropriate domain manager
Review equipment inventory for affected items
Send FYI email to risk manager
Yes
Is alert urgent, used at Scripps, high colume and used during invasive proceudres?
No
Attach inventory information and work notes. Forward alert to VAD coordinator for action
Review alert, inventory information, equipment logs, add instructions for responders if applicable (response action)
Is alert applicable to Scripps?
No
Close Recall
Yes
Send FYI email to afftected department managers
Forward to responder
No
Will VAD coordinator perform response?
Yes
Perform Response and Document

How do we respond?

- Recall Alert Notification
- Pull Purchase Data from past 2 yrs.
- Pull Clinical Data from Health Record
- Distributor – pull and replace
- Cart Level Detail – pull and replace
- Provider notification – patient list

URGENT: Medical Device Recall

Philips Respironics

CPAP and Bi-Level PAP Devices

Sound Abatement Foam
Susceptibility to Degradation and Volatile Organic Compound Emission

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First name	Last name	Date of birth	Setup date	Location	Patient status	Compliance status	Device serial number	Device name	Care team
[redacted]		12/30/1942	6/22/2021	SUPER CARE MEDICAL SUPPLY, Supercare	Active	Compliant	D13134104802F2	DreamStation 2 Advanced	[redacted]
		9/24/1961	6/21/2021	SUPER CARE MEDICAL SUPPLY	Active		D131318699AAED	DreamStation 2 Advanced	
		8/14/1973	6/18/2021	SUPER CARE MEDICAL SUPPLY	Active		D131318733A21B	DreamStation 2 Advanced	
		2/10/1970	6/18/2021	SUPER CARE MEDICAL SUPPLY	Active	Compliant	D13131915993F3	DreamStation 2 Advanced	
		10/21/1966	6/17/2021	SUPER CARE MEDICAL SUPPLY	Active		D1307701472ED7	DreamStation 2 Advanced	
		9/18/1958	6/17/2021	Scripps Clinic Medical Group, Inc.	Active		J161910197372	DreamStation	

EPIC Patient Data Identified:
5,349 Patients with CPAP/BIPAP Recalled Devices
8 Sleep Study Devices Recalled

URGENT: Medical Device Recall

Philips Respironics

Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models

Site	V30 (Recalled)	V60	Resmed (Auto titration capable)	Omni lab (Recalled)	Rem Star (Auto titration capable)	Usage	V30 (Cpap for OSA)	V60 (Bipap)	Pt own Cpap	NEED auto titration	Need to replace V60 use
Encinitas	8	15	0	0	0		6	8	2	2	6
Green	12	10	2	0	0		4	1	2	0	4
La Jolla	15	27	1	0	2		6	10	3	2	6
Mercy	4	18	2	3	0		4	6	2	2	4
Chula Vista	2	10	0	0	0		1	4	1	2	1
Totals	**41**	**80 (includes 16 rentals)**	**5**	**3**	**2**		**21**	**29**	**10**	**8**	**21**

Communication Talking Points for Respiratory Care Practitioners (RCP)

- All Home CPAP units are to be checked by RCP
- Verify Serial Numbers on Philips Website
  - If serial number listed, cannot use tubing or mask
- Verify patient compliance and active sleep disorder diagnosis
- Consult with Physician to use V60 for Nighttime CPAP
- If serial number NOT recalled, document in health record
  - “Serial # was checked via Philips Website and not recalled”

Clinical Practice Alert

Attention MD, Nursing, and Respiratory Staff
Effective Immediately

CPAP Recall affects Scripps and Patient's Owned Devices

Situation	Philips Respironics has recalled several CPAP devices due to an issue with the foam used for sound abatement.
Background	• Affected CPAP devices are used in Scripps Sleep Labs, in inpatient units, and procedural areas. • Patients often bring them from home hospital to use during hospital stay.
Assessment	• In the interest of patient safety, Scripps has removed all affected devices from service and will not allow the use of patient's affected home device.
Recommendation	• See attached manufacturer list of recalled device models and description of the problem. • RN to alert Respiratory staff to evaluate patient's own machine upon admission. • Respiratory to provide comparable Scripps machine for use during hospitalization if needed. • Encourage the patient to use the replacement machine for their "comfort and safety". If they refuse, consult the provider for orders related to treatment and/or monitoring. • Patients who would like further information, should refer to their primary care physician and Philips Respironics website: *https://www.philipssrcupdate.expertinquiry.com/registration*

Dear @M@ @LNAME@,

We have been notified that Phillips Respironics has issued a recall notification for several devices, including the Dream Station 1. Philips Respironics is working to replace or repair these recalled devices, but we understand that you have questions and concerns.

We suggest that you visit the Philips Respironics website at:

https://www.usa.philips.com/healthcare/e/sleep/communications/src-update

The website states that you should "Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks." At this time, we recommend you continue to use your CPAP until repair or replacement can be arranged, or we receive additional information about the potential risks.

We also recommend that you discontinue using any ozone-related cleaning products and follow the manufacturer's instructions for cleaning.

We are closely monitoring this situation and will update our patients as we receive additional information. I will also forward your message to *** for further consideration.

Please register your device and submit a claim at:

https://www.philipssrcupdate.expertinquiry.com/

Sincerely,

Scripps Sleep Center

Communication Talking Points for Providers

- Providers given standardized email template
- Emails sent out to patients with recalled devices
- Written letters were mailed to their homes as a secondary measure
- Medical Office staff given talking points for phone calls

Meet Bob Simpson!

His HVAD Controller Lot# is on the recall list

Recalled Product

- HeartWare HVAD Battery Cables, Data Cables, Adapter Cables and Controller 2.0 Ports
- Product Numbers:
  - Medtronic HVAD Controller AC Adapter: 1425AU, 1425CA, 1425DE, 1425GB, 1425IL, 1425IT, 1425US, 1430AR, 1430AU, 1430CA, 1430CH, 1430DE, 1430GB, 1430IL, 1430IN, 1430IT, 1430JP, 1430US
  - Medtronic HVAD Controller DC Adapter: 1440
  - Battery: 1650DE
  - Alarm Adapter: 1450
  - Monitor Data Cable: 1575
  - Controller: 1400, 1401, 1403, 1407, 1420

Bob provided us written permission and consent to use his picture for the FDA PEAC presentation.

Notification Process for the HVAD Recall

- VAD Program Manager receives call from Account REP
- VAD coordinator notified all care team members
- FDA Notification received via email
- 7 Patients identified; 2 with recalled controller LOT #
- Within 24 hours of the FDA notification, all patients notified
- Home Visit- Neon Pink Stickers placed on the 2 recalled controllers
- 24/7 VAD troubleshooting emergency call line education

LEARNING UDI
COMMUNITY

AHRMM
Advancing Health Care through
Supply Chain Excellence


Thank
you!