



Inequity regarding Disbursement of Refurbished /Replacement Positive Airway devices (PAP) in the recent Respironics PAP recall

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Phillips Recall

About 5 million PAP and assisted ventilation devices

June 2021: Phillips device recall announced

Particulates released as well as off gassing of Volatile organic compounds from polyester containing polyurethane sound abatement foam

Dates	MDRs Received	Reports of Deaths in MDRs
April 1, 2021 - April 30, 2022	>21,000	123
May 1, 2022 – July 31, 2022	> 48,000	45
August 1, 2022 – October 31, 2022	>21,000	96
November 1, 2022 – December 31, 2022	> 8,000	81
January 1, 2023 – March 31, 2023	> 5,000	40

<https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due#risk>

Access July 27, 2023

Recall Challenges and Delivery Concerns

Magnitude of the recall and Significant supply limitations for replacement or refurbished devices

Months to years to replace

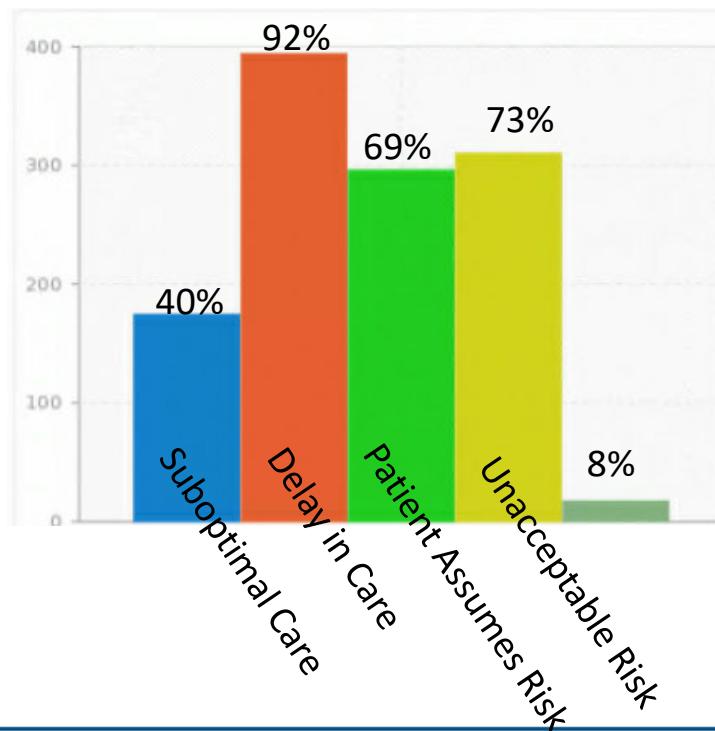
Parse, disproportionate, and fragmented communication (especially for the vulnerable)

Choices: Maintain therapy versus discontinue treatment versus costly alternative

The AASM Members Survey

- National Survey :2 year Philips Device Recall Pulse Survey
- 427 participants comprised of Physicians, Physician Assistants, Sleep Technologists, Dentists, etc
- Broad Audience: Academic institutions (34%), Nonacademic (31%), solo practices (34%), Military based (5%), etc
- All 50 states represented

Choices: How did patients address the recall?



- Alternative therapies
Oral Appliances/Surgery
- **Alternative Brand of PAP**
- No acceptable choice/
remain on Recall
- Stopped Therapy

Determinants of Population Inequity During the PAP Recall

AASM and other Academic Societies Inequity Concerns raised

June 25th, 2021:

- AASM members provided real-life anecdotes

Vulnerable populations were disproportionately affected by recall

- Later, AASM, ATS, ACCP and AAN reported similar concern

Population and Determinants

Population	Determinant
Elderly, Underinsured and Underserved	Dropping in and out of Health care
Low socioeconomic status / Physical limitation	Difficulty accessing Information regarding recall and Mitigation process
Low technology Literacy /Pregnant/Pediatrics	Need Ancillary Support (not always available)

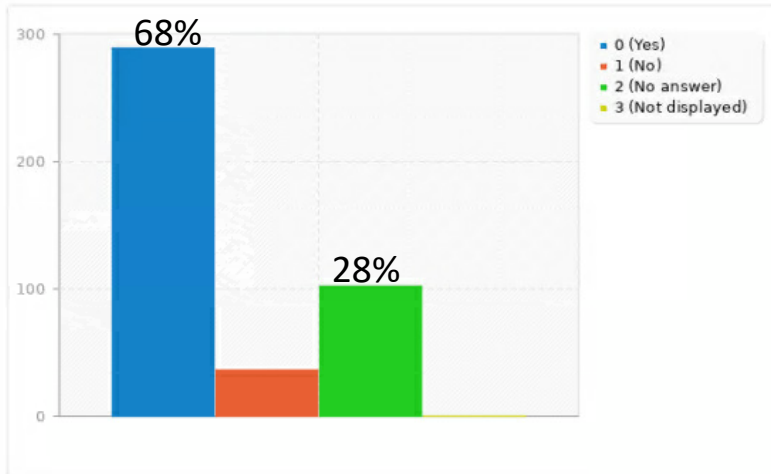
AASM Survey Physician's Response to the Phillips Recall

Magnitude Remains

An Opportunity for Industry Change

Summary for G01Q02

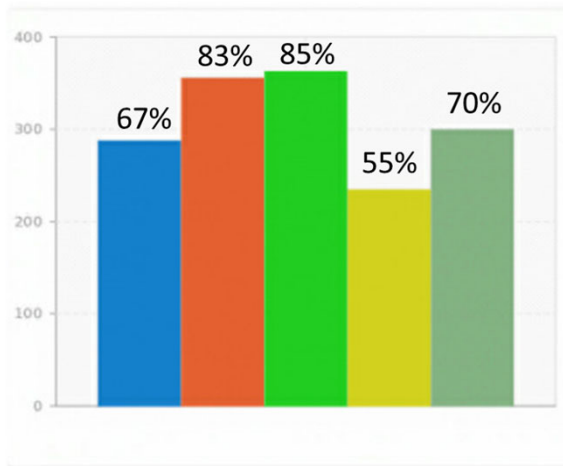
Do you currently encounter individuals who still possess a recalled PAP device? This could include any encounter, including one-time encounters of any type (consult, clinic, message, etc).



Circumstance Include:

Answer	Count	% of Respondents
Patient did not understand the process	223	52.22 %
Patient did not have the means / capacity to facilitate electronic communication	140	32.79%
Language Barrier	64	14.99%
Individual Met with barriers (need a physician)	144	32.32%

The effect of the PAP recall on Patients Perceptions



- 0 (loss of trust in care)
- 1 (confusion regarding care)
- 2 (delays in care)
- 3 (negative health outcomes (direct or indirect) related to the recall)
- 4 (opportunity cost related to recall: time and effort spent on recall meant less time for competing needs)

AASM Systematic Causes led to PAP Delivery Inequity



Absence of industry wide tracking technologies in devices



No guidelines exist to mitigate inequities



Environment favors :

Means to purchase other pap devices

Amplified inequities of poorly covered alternative therapies: MAD, SX

Lack of transparency of replacement protocol



Erode of public confidence

Key Points

Impact of the Phillips PAP recall is ongoing...

- Over 70% of respondents treat patients with recall needs.

Inequity in alternative therapy approaches exists..

- Cost and means to receive alternatives create inequity
- 55% observed negative health care outcomes

AASM members report a loss of trust among patient

- Confusion in the process (83%), Delays in care (85%), and loss of trust in (70%)

Recommendations



REGULATORY OVERSIGHT
GUIDELINES FOR RECALL



POST MARKETING
OVERSIGHT



DEVICE TRACKING