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DURABLE MEDICAL EQUIPMENT

# Rapid response to medical device recalls: an organized patient-centered team effort

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As more patients depend upon mechanical or electronic technologies for treatment, medical device recalls—like the recent recall of common positive airway pressure treatment devices—impact millions of patients, often causing significant anxiety, extra costs, and interruption of care for patients. When recalls require health care and/durable medical equipment providers to be part of the solution, the burden on practices and businesses can be significant, creating strains on access for new patients and on limited medical supplies. We have observed that having an established and well-organized medical device recall plan in place allows for a rapid response, decreased practice burden, and reduced provider stress. Coupling the organized response with proactive, empathic, and clear communication with patients reduces their anxiety, provides clear directions for how to address the issue constructively, and reduces reactive communications. We share what we believe are key components of a medical device and produce recall procedure as we describe our institutions response in hopes that others can build on these basics as they design their own response plans.

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## INTRODUCTION

Each year, approximately 30–40 medical device recalls take place in the United States.[1,2] Such seemingly small numbers create significant impacts on millions of patients around the world. We consider, for instance, the recent medical device recalls issued by Philips Respironics for its sleep and respiratory care products on June 14, 2021.[3]

## THE SITUATION

Philips Respironics publicly announced that several of its popular products—certain continuous positive airway pressure (CPAP), bilevel positive airway pressure (BPAP), and mechanical ventilatory devices—emit dangerous particles and chemical emissions from the polyester-based polyurethane sound abatement foam used inside them.

Shortly after the announcement, the US Food and Drug Administration (FDA) issued 2 separate Class I recalls, the most serious type of recall, for Philips Respironics sleep and respiratory care devices on June 30, 2021.[4,5] The top concern was that some of the chemical emissions were classified as carcinogens, thereby placing patients at risk of serious injuries or death.[6] Other major adverse effects reported included respiratory distress, inflammation, hypoxia, and hypercarbia.[4]

Philips Respironics estimated that the recall impacted more than 16 million domestic and international patients.[3] As many as 9,000 Mayo Clinic patients, approximately 60 of whom were pediatric patients, used the recalled CPAP and BPAP devices regularly.

Although Philips Respironics provided long-term resources, such as device registration and future repair and replacement plans for affected users,[3] little information was shared about immediate actions that patients could take for their safety other than to contact their providers for recommendations. Furthermore, the spectrum of risks related to discontinuing or continuing the recalled devices was in our opinion undercommunicated, causing unclear directions for patients and providers.

## MAYO CLINIC'S RESPONSE

Fortunately, Mayo Clinic already had a procedure for medical device and product recalls in place when Philips Respironics reached out to our supply system and the clinic's Office of Patient Safety about the faulty sleep medicine and respiratory devices. This procedure helped staff quickly address the CPAP and BPAP recall, serve patients with efficient personalized care, and reduce negative impacts on the practice, all in an organized and consistent fashion.

When medical devices are recalled, patients experience uncertainty and anxiety with evolving and often conflicting updates regarding their safety and what steps they need to take. With the Philips Respironics CPAP, BPAP, and mechanical ventilatory device recalls, Mayo Clinic's primary lessons from prior recalls that guided actions were (1) ensuring centralized awareness of device recalls, (2) helping staff to visualize their

proactive approaches to the situation, and (3) using empathic communications when informing patients about the recall. We believe these lessons may serve other health care systems as they develop medical recall response systems.

## LESSON 1: ENSURE CENTRALIZED AWARENESS OF DEVICE RECALLS

Recall notifications can enter different parts of an organization from many directions. For example, the device manufacturer, pharmaceutical company, or FDA may send notifications to a limited or a broad list of contacts. Other communication routes may include manufacturer or vendor letters, mass media coverage, professional society news updates, or word-of-mouth communication from patients and academic peers.

These unpredictable streams of information create an opportunity for human error via poorly organized internal communication. One portion of the organization may falsely assume that the other is already aware and addressing the situation. Such a lack of coordination can cause reactive delays for the organization and a poorly organized response, potentially causing harm to patients. Poorly coordinated responses may lead to diverse and/or conflicting communication with patients and staff, fueling anxiety and stress.

To avoid this miscommunication scenario, Mayo Clinic's recall management procedure instructs staff to forward such notifications to the recall coordinator in the Supply Chain Management department and specialists in the Office of Patient Safety. The coordinator maintains an email distribution list and notifies all members of the recall process staff to implement a set of standard next actions. The coordinator also logs a priority alert in Mayo Clinic's recall management system database, which tracks and archives all events. The assigned recall (FDA Class I, II, or III) prompts the required response time for downstream processes.

In this instance, the FDA Class I recall for Philips Respironics required a response from all affected parties (Supply Chain Management, Office of Patient Safety, Mayo Clinic Stores [a durable medical equipment provider], Mayo Clinic Sleep Medicine Centers, the Pulmonary Medicine Divisions, Primary Care, Public Affairs, Legal, and Nursing) within 1 business day.

## LESSON 2: HELP STAFF VISUALIZE A REASONED PROACTIVE APPROACH

Clinical information was limited at the beginning of the Philips Respironics situation. Ideally, medical device recalls involve exchanging faulty devices with similar equipment of a different model or brand; however, neither Philips Respironics nor its competitors had the inventory for timely replacements.

In lieu of issuing replacements, the manufacturer separated patients into 2 populations for the following advice:

1. Patients with "certain ventilators and BiPAP machines" for breathing assistance should "not stop or alter prescribed therapy until talking to care providers."[3]
2. Patients with "BiLevel PAP and CPAP devices" should discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks.[3]

In other words, Philips Respironics advised both patient populations to discuss next steps with their providers, but clinical resources were not available to support these providers with making decisions regarding their patients' device-assisted therapies. In addition, the weighed risks related to discontinuing or continuing recalled devices were unknown, causing unclear direction for providers trying to respond to various clinical situations.

Within a few days of the recall notice, the Mayo Clinic Sleep Medicine Specialty Council, along with the Office of Patient Safety and other sleep medicine specialists, created a clinical decision tree to address these concerns (**Figure 1**). The staff identified 3 domains to stratify Mayo Clinic's patients:

1. Patients using certain noninvasive ventilatory support devices.
2. Patients with clinical conditions that might deteriorate without positive airway pressure, leading to harm.
3. Patients with occupational or operational functions that required maximal alertness for safety.

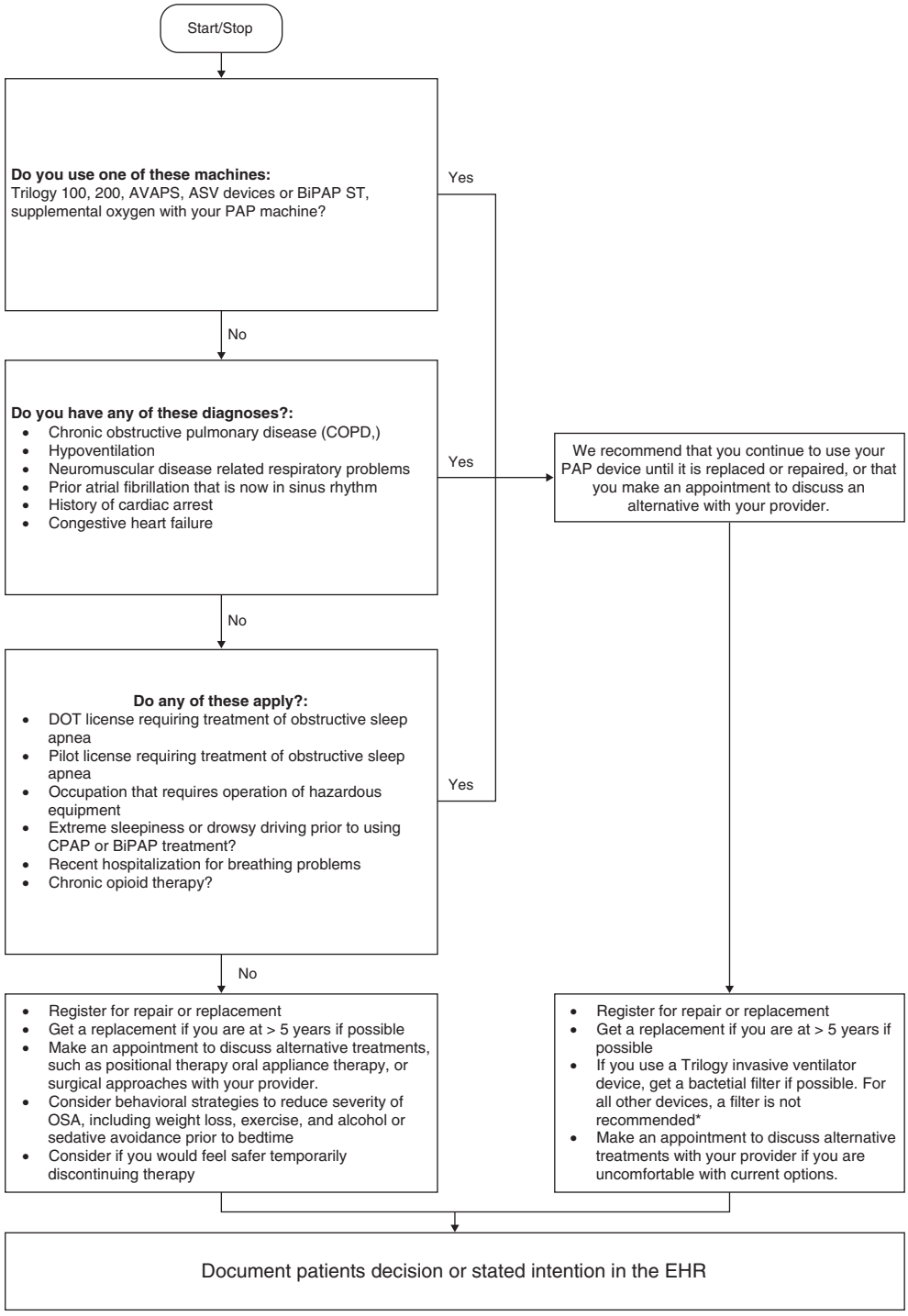
We were able to link patient-specific device registration back to our internal electronic health record using prestructured templates that match key demographic and health information to identify most patients who would be affected by the recall with the intention of proactively contacting those patients. At the same time, the specialty council developed protocols that empowered closely allied nurses to assist patients as they contacted the medical center, via either phone or portal messages. Experts created and preapproved intake questions for nurses to use while obtaining the needed information and documenting decisions in the electronic health records. The preapproved decision pathways and recommendations helped many patients make decisions about how they wanted to approach the recalls. However, many patients still required discussions with their providers.

The specialty council also communicated expectations to all impacted care teams that if needed, sleep medicine specialists could provide e-consults or clinical visits. Because of the need for increased access, in our largest facility in Rochester, Minnesota, providers opened up 15-minute appointment slots, either face-to-face or via telehealth, specifically designed to address the recall issues. The appointments ended with informed decisions and confirmation that the patients' expectations were met.

## LESSON 3: USE EMPATHIC COMMUNICATIONS TO INFORM PATIENTS ABOUT THE RECALL

Mayo Clinic's staff strive to approach complex patient conversations with empathy, meaning that the message senders focus on understanding the other person's experience from that person's perspective. Use of the 3 R's technique—reflect, rationalize, and reassure—establishes respect and value for the message receiver.[7] This form of empathy is essential to placing the needs and perspectives of the patient first.

**Figure 1—**Decision flow chart.




This decision flow chart was created for medical staff—registered nurses or licensed providers—to discuss the situation with patients who contacted us in response to the recall event. We were able to push questionnaires via our secure portal to gather the answers to these questions. If completed, the answers could be used to facilitate the discussion. We asked that at the conclusion of each contact the patient's stated intentions for next steps be documented in the electronic health record to assist the next person dealing with these issues. Scripted phrases were made available to help standardize the documentation of the interactions, reducing clerical burden and providing a consistent framework for communicating the information in the record. Note: At the time this flow chart was developed and first deployed, filters were a recommended safeguard for the particulate contaminants. This guidance changed as more national guidance was issued. *Trilogy ventilator labeling recommends that a main line outlet bacteria filter be used on Triology devices whenever the device is used for invasive therapy. The inline bacterial filter (MPN: 342077 or C06418) with minimally tolerated humidity is recommended. It may reduce exposure to degraded sound abatement foam particles, although bacterial filters will not reduce exposure to potential volatile organic compounds. AVAPS = average volume-assured pressure support, ASV = adaptive servoventilator, BiPAP = bilevel positive airway pressure, BiPAP-ST = bilevel positive airway pressure with spontaneous or timed mode, CPAP = continuous positive airway pressure, DOT = US Department of Transportation, EHR = electronic health record, OSA = obstructive sleep apnea, PAP = positive airway pressure.

We engaged our communications experts, who used this technique in 2 separate letters that alerted patients about the medical device recall. The first letter went to patients whose records confirmed them as owners of a recalled Philips Respironics device that fell into the first and more critical category.[8] We judged that adaptive servoventilators would be rare but might be critical for patients, who often have heart failure comorbid with central sleep apnea. The second went to users of CPAP and BPAP who had an unknown model or who were likely using a positive airway pressure device for obstructive sleep apnea.[9]

The following definitions and examples illustrate how the patient recall notifications applied empathy:

- **Reflect:** Imagine yourself in the patient's shoes. Show in your first sentence that you understand how the patient is likely to feel about what you are going to say. Challenge yourself to do this without using terms like "I understand . . . ." This validates their perspective and shows that we believe their views are important.

**Example from Mayo Clinic's letters to patients:** Thank you for choosing Mayo Clinic as your destination for sleep medicine and respiratory care. Your safety is our top priority. That's why we're writing to share new information regarding your sleep and respiratory care products.[8,9]

- **Rationalize:** Share with the patient the reasons why the situation is as it is.

**Example from Mayo Clinic's letters to patients:** The manufacturer of your device, Philips Respironics, issued a recall on June 14 for specific continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiLevel PAP) devices and mechanical ventilators. These devices are used by patients with sleep breathing disorders, such as sleep apnea, or those who need chronic noninvasive respiratory ventilatory support . . . . Philips recalled these devices due to concerns that patients could be exposed to dangerous particles and chemical emissions from the foam material used inside certain Philips devices.[8,9]

- **Reassure:** Let the patient know that decisions made about their care are centered on their best interests. Inspire confidence by speaking positively about our commitment to relevant care, be specific about what to expect, and remind them that Mayo Clinic will continue to be a resource.

**Example from Mayo Clinic's letters to patients:** The Mayo Clinic Sleep Medicine Specialty Council, along with Mayo Clinic Patient Safety and Risk Management and other sleep medicine specialists, have developed Mayo Clinic's approach to assisting you and your care team with this safety recall . . . . Mayo Clinic remains dedicated to providing the highest-quality care in managing and ensuring the safety of your sleep and respiratory care device. We will continue to monitor the situation and share new information as it becomes available.[8,9]

In addition to raising patients' awareness about the Philips Respironics medical device recall, Mayo Clinic included a series of independent actions that patients could take to address their concerns and begin a revised care plan immediately. This initiative addressed the negative emotions that patients may feel about a situation being out of their control.

An additional feature of our communications in general is to invite patients to discuss clinical questions with Mayo Clinic. They were referred to the manufacturer for matters related to the device—in this case, registering their device and inquiries about payments for new equipment.

Although it is not part of the communication and internal process, we are committed to reporting device-related patient safety events to the Medical Product Safety Network, an adverse event reporting program sponsored by the FDA's Center for Devices and Radiological Health.[10] We believe that this is one of the best ways to help improve device safety.

## CONCLUSIONS

We believe that having a plan in place at the time of device recalls enables a more thoughtful and effective response by health care providers. It is also important to learn from each recall and to incorporate lessons learned into future responses. In this regard, we could have avoided unsupported advice related to the bacterial filters if we had paid more attention to the controversy about that advice at the time. We did explain to patients that the filters may reduce exposure to foam particulate matter but would not reduce exposure to the chemical toxins of greater concern. However, subsequent recommendations were changed in view of uncertain benefit and risks. We also realized that because there was very little information about the timeline for remediation or replacement, transparency about that timeline in early communications may have been more reassuring to patients than unrealistic expectations.

At the time of writing this article, it was the beginning of August 2021 and the aftermath of 2 FDA recalls on Philips Respironics CPAP, BPAP, and mechanical ventilatory devices continued to unfold. Although the future remains largely uncertain regarding this issue, Mayo Clinic's proactive efforts have seemed to help ease patients' worries amid the uncertainty.

Quantitative data suggest that patients' needs are being met with a downward trend of calls to care teams. In early July 2021, Mayo Clinic's Rochester campus received approximately 200 contacts per day. By the week of July 19, these call volumes went down to 100 contacts per day. Since then, the amount of calls continued to decrease. Qualitatively, numerous patients provided positive feedback and expressed their gratitude for Mayo Clinic's assistance with navigating the sticky web of correcting faulty medical devices.

Innovation is leading to increased use of medical devices in health care, often with dramatic benefit to patients. FDA-approved devices already undergo significant testing, but despite this oversight FDA and manufacturer recalls seem increasingly frequent and mostly related to quality issues.[11] Many are unannounced and therefore become highly reactive for health care organizations and patients. We believe that the strategies and communication lessons discussed here may serve

for health care organizations to create strategic recall plans that ensure consistent, effective, and rapid responses to ease impact on patients and care teams.

## ABBREVIATIONS

BPAP, bilevel positive airway pressure
CPAP, continuous positive airway pressure
FDA, Food and Drug Administration

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## SUBMISSION & CORRESPONDENCE INFORMATION

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## DISCLOSURE STATEMENT

The authors have no relevant relationships with any commercial interests to disclose. The authors report no conflicts of interest.