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Philips Respironics field safety notice announced on June 14, 2021

Third party epidemiological studies
Frequently Asked Questions related to the 2022 Swedish study by Palm et al.
- as of July 8, 2022

Together with qualified third-party experts, Philips Respironics is monitoring and reviewing epidemiological study publications that may be relevant for the June 2021 field safety notice for specific CPAP, BiPAP and mechanical ventilator devices.

Independent of Philips Respironics, in December 2021, an analysis was published in the American Journal of Respiratory and Critical Care Medicine that found no significant difference in the risk of incident cancer among obstructive sleep apnea (OSA) patients who used a Philips Respironics PAP device as compared with OSA patients who used a PAP device from other manufacturers, or OSA patients without treatment. The analysis and conclusion were based on data from a large multi-center cohort study in Canada involving 6,903 OSA patients on PAP devices between 2012 and 2020, including 1,220 Philips Respironics PAP users, with a median follow-up time of 7.5 years.

More recently, and also independent of Philips Respironics, an analysis was published online in the European Respiratory Journal in May 2022 that concluded that sustained and adherent CPAP therapy of OSA using Philips Respironics devices, compared with other manufacturers' devices, was not associated with an increased risk of cancer. The analysis and conclusion were based on data from a large multi-center cohort study in France involving 4,447 OSA patients on CPAP devices between 2007 and 2018, including 1,648 Philips Respironics CPAP users, with a median follow-up time of 7.2 years.

Philips Respironics has also noted and reviewed the 2022 Swedish study by Palm et al., which was published in the European Respiratory Journal in May 2022.

Can Philips Respironics comment on the Swedish study and its conclusions? What are the main limitations of the study?

Philips Respironics and the team of third-party experts identified significant methodological and reporting limitations in the Swedish study that are also partially acknowledged by the authors of the study. These limitations, which prevent the Swedish study from providing insight on causal health effects of Philips Respironics CPAP use, were also pointed out in the French analysis mentioned above.

The major limitation of the Swedish study is the reliance on county-level ecological data on type of CPAP device use, without any individual patient-level data on CPAP type or history. That is, this study has no information on what type of CPAP device was used (Philips Respironics or otherwise) by any individual patient.

Instead, the Swedish study compares patients living in counties prescribing ≥80% CPAP devices with polyurethane foam (PUF-CPAP) vs. patients living in counties prescribing <10% PUF-CPAP devices. Any differences between the two populations cannot be causally attributed to PUF-CPAP vs. non-PUF-CPAP or Philips Respironics vs. non-Philips Respironics devices, because there are many

potential differences (called “confounders”) such as health status, socioeconomic status, health care access and usage, smoking history, etc., that have not been taken into consideration and could be responsible for dissimilar health outcomes between the two populations.

Do the Canadian and French studies referenced above have similar limitations?

No, the Canadian and French studies do not have this limitation because they both have individual-level information on the type of CPAP device used by each patient, and the French study even had information on CPAP device adherence. Moreover, both studies controlled for multiple patient-level confounders characterized through survey and health administrative data.

What is Philips Respironics’ view on the conclusion of the Swedish study that polyurethane foam (PUF) in CPAP may contribute to increased airway symptoms and obstructive lung disease (OLD) exacerbations?

Although more prescriptions for medications to treat OLD were received by obstructive sleep apnea patients with OLD who lived in counties prescribing mostly PUF-CPAP devices, compared with those living in counties prescribing mostly non-PUF-CPAP devices, there was no statistical difference in the rate of hospitalization for OLD. The latter outcome was the only endpoint examined in the study that was specific to OLD.

More importantly, because the study did not compare individual patients who used PUF vs. non-PUF or Philips Respironics vs. non-Philips CPAP devices, any observed differences in health outcomes cannot be causally attributed to PUF in CPAP or the brand of CPAP device, since many unadjusted confounders could be responsible for these differences between the two populations.

It is worth adding that over the course of the study, the rate of newly developed OLD was statistically indistinguishable between counties using mostly PUF-CPAP and mostly non-PUF-CPAP devices.

What is Philips Respironics’ view on the Swedish study regarding the all-cancer and lung cancer incidence related to CPAP device use?

The study shows no statistical difference in the occurrence of all cancers or lung-cancer between the two sets of counties after accounting for county-level smoking rates.