

# Withdrawal of stop-smoking pill could lead to thousands of avoidable deaths

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The disruption to the supply of a prescription medicine that helps people stop smoking may have led to thousands fewer people quitting each year in England, which will lead to avoidable deaths in future, suggests a new

study led by UCL (University College London) researchers.

Varenicline (also known as Champix) is one of the most effective treatments to help smokers quit. It works by reducing cravings for nicotine and easing withdrawal symptoms. But its distribution was paused in July 2021 in the UK and Europe as a precaution after higher than expected levels of a potentially harmful substance were found in the tablets.

The new study, published in the journal *Addiction*, looked at survey responses and NHS prescription data to track how use of the drug had declined in England, finding it had fallen from 3.9% of all quit attempts in the second half of 2021 to 0% of quit attempts by the end of 2022.

The researchers estimated that over a year with no [varenicline](#) prescriptions, this would mean 85,800 people not taking the drug who might otherwise have done so.

As a result of smokers moving to less effective smoking cessation aids or not using any medication or nicotine replacement at all to help them quit, an estimated 4,200 fewer would have stopped smoking for good in a year, the researchers found. They estimated this would lead to 1,890 more smoking deaths for each year varenicline was unavailable. These deaths would occur over coming decades, with lifelong smokers losing an average of over 10 years of life compared to non-smokers.

Lead author Dr. Sarah Jackson, of the UCL Tobacco & Alcohol Research Group, said, "Varenicline is a gold-standard prescription treatment for smokers trying to quit. The disruption of its supply in the UK and Europe likely reduced the number of people successfully stopping smoking, which will lead to more preventable deaths. Our study gives a sense of the scale of this.

"Fortunately, another prescription drug called cytisine became available in the UK in January that is similarly effective to varenicline and could help fill the gap. Efforts to promote awareness of cytisine among smokers and prescribers may help to reduce smoking deaths over the long term."

The researchers used data from the Smoking Toolkit Study, in which a different sample of 1,700 adults in England (who are representative of the population) are interviewed each month. Use of varenicline fell to 0.8% of all quit attempts in the second half of 2022, the surveys suggested, with no quit attempts involving varenicline in the last quarter of the year.

Meanwhile, data from GP surgeries in England suggested varenicline accounted for just 0.1% of smoking cessation prescriptions in December 2022.

Some smokers moved to using prescription drug bupropion or NRT ([nicotine replacement therapy](#)), but these tools are estimated to be around 40% less effective than varenicline at helping people quit.

While prescriptions for bupropion (another smoking cessation medication) doubled between July 2021 and December 2022, the researchers also found a 35% drop in monthly prescriptions for smoking cessation medicines overall, comparing the periods June 2018-June 2021 with July 2021-December 2022.

The researchers therefore estimated about 35% of would-be varenicline users would not be using any medication at all to help them quit, with the remaining 65% using bupropion or NRT.

The distribution of varenicline was paused by the manufacturer, Pfizer, because of a higher than acceptable level of (potentially carcinogenic)

nitrosamines in the tablets.

Following action from UK and EU regulators, health care staff in the UK were advised to return batches of the drug to their supplier in October 2021. Generic versions of the drug are currently available in the US, Canada and Australia but not in the UK.

Nitrosamines, which are thought to increase [cancer risk](#) if levels of exposure are high, are also present in tobacco.

The researchers noted that if the nitrosamines in the tablets were similarly carcinogenic to tobacco-specific nitrosamines, a standard 12-week course of Champix (varenicline) would give an equivalent dose to smoking 198 cigarettes (18 days of smoking at a typical consumption of 11 cigarettes day). This is a much lower level of risk than continuing to smoke in the long term.

Senior author Professor Lion Shahab, of the UCL Tobacco & Alcohol Research Group, said, "The withdrawal of varenicline has had substantial unintended consequences. Our study suggests it will lead to thousands more [avoidable deaths](#) from smoking in England alone. Industry and regulators acted with caution, leading to a life-saving smoking cessation medicine becoming unavailable. Perhaps they did not fully consider the effects this would have on the health of continuing smokers, who are exposed to a much higher level of risk than that likely caused by nitrosamine impurities in varenicline.

"It is imperative that non-nicotine based smoking cessation pharmacotherapies, such as varenicline, bupropion and—most recently—cytisine, are made widely available to smokers who do not wish to use nicotine-containing products, including NRT or e-cigarettes, to help them quit smoking."

**More information:** Impact of the disruption in supply of varenicline since 2021 on smoking cessation in England: a population study, *Addiction* (2024). [DOI: 10.1111/add.16485](https://doi.org/10.1111/add.16485)

Provided by University College London

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