MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Chantix (Varenicline): Safety Communication - Updated Safety Review On The Risk of Cardiovascular Adverse Events

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FDA公告一項大型、綜合分析研究(meta-analysis)之結果：使用戒菸藥品Chantix (varenicline)的受試者，相較於使用安慰劑的受試者，有較高的嚴重心血管事件發生率(包含心血管疾病相關隻死亡、非致命性心臟病發作與非致命性中風)。這些嚴重心血管事件在試驗組、對照組的發生率均屬罕見，兩組別沒有統計上的顯著差異。這種結果表示仍無法確認Chantix (varenicline)是否會增加額外的嚴重心血管風險。

醫療人員應權衡Chantix的風險。重要的是，吸煙是心血管疾病的主要危險因素，Chantix可有效地幫助患者戒菸長達一年。戒菸對健康的好處是直接的和實質性的。

服用Chantix的患者如果有新的或加重心腦血管疾病的症狀，如胸悶、胸痛、呼吸短促、行走時小腿疼痛，或突然無力、麻木、說話困難，或有任何問題或疑慮，均可詢問醫療人員。

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AUDIENCE: Family Practice, Cardiology, Patient

ISSUE: FDA is informing the public about the results of a large, combined analysis (called a meta-analysis) of clinical trials that compared patients who received the smoking cessation drug Chantix (varenicline) to patients who received a placebo (an inactive treatment). A higher occurrence of major adverse cardiovascular events (a combined outcome of cardiovascular-related death, nonfatal heart attack, and nonfatal stroke) was observed in patients using Chantix compared to placebo. These events were uncommon in both the Chantix and placebo groups, and the increased risk was not statistically significant, which means it is uncertain whether the excess risk for the Chantix group was due to the drug or due to chance.

BACKGROUND: Chantix is a prescription medicine used to help adults quit smoking that works by blocking the effects of nicotine (from smoking) on the brain. FDA first notified the public about a possible increased risk of cardiovascular adverse events with Chantix in its June 2011 Drug Safety Communication (DSC). FDA required the manufacturer of Chantix to conduct the meta-analysis to further evaluate the cardiovascular safety of the drug, and believes it is important to let health care professionals and patients know about the results of this study. The meta-analysis findings of cardiovascular risk are similar to the findings in the smoking cessation clinical trial of patients with stable cardiovascular disease that was described in FDA's June 16, 2011 DSC. The Warnings and Precautions section of the Chantix label has been updated to include the results of the meta-analysis.

RECOMMENDATION: Health care professionals are advised to weigh the risks of Chantix against the benefits of its use. It is important to note that smoking is a major risk factor for cardiovascular disease, and Chantix is effective in helping patients to quit smoking and abstain from it for as long as

one year. The health benefits of quitting smoking are immediate and substantial.
Patients taking Chantix should contact their health care professional if they experience new or worsening symptoms of cardiovascular disease, such as chest pain, shortness of breath, calf pain when walking, or sudden onset of weakness, numbness, or difficulty speaking. Patients should also contact their health care professional if they have any questions or concerns about Chantix.