IMPACT-AFib: Implementation of Stroke Prevention in Atrial Fibrillation

Purpose: To determine whether education on stroke prevention in atrial fibrillation (AF) among AF patients and their providers can result in increased use of oral anticoagulants (OAC) for stroke prevention among those AF patients with guideline-based indications for oral anticoagulation (CHA_2DS_2-VASc score of 2 or greater).

Trial Design: N= ~ 80,000, prospective, randomized, and open-label education intervention trial , using FDA-Catalyst Sentinel infrastructure. In the early intervention group, patients and their providers received one mailing at the start of the trial.

Primary Endpoint: Difference in the proportion of AF patients with at least one OAC prescription fill over the 12-month trial follow up.

Proportion of patients who initiated OAC	Early Intervention- Patient provider mailing at trial start (N= 23546)	Delayed Intervention- Control (N= 23787)	Adjusted Odds Ratio (95% CI)
At 1 year	2328 (9.89%)	2330 (9.80%)	1.01 (0.95, 1.07)
At 183 days	1403 (5.96%)	1362 (5.73%)	1.04 (0.96,1.12)
At 90 days	769 (3.27%)	738 (3.10%)	1.05 (0.95, 1.16)
At 42 days	394	361	1.09 (0.94, 1.26)

Results: Among a population with a guideline indication for OAC for stroke prevention with AF, there was no statistically significant difference in rates of OAC initiation at 1 year with a single education mailing and the rates of OAC initiation was low. It was feasible to identify, enroll, and obtain outcomes through this novel study design using the FDA-Catalyst Network.

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