Quantify Use of ANTicoagUlation to improve Management of Atrial Fibrillation

NOPRODAFL0001/QUANTUM AF
Study Summary

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Sponsor: Janssen Scientific Affairs, LLC

Information provided by: Janssen Scientific Affairs, LLC

Purpose: The primary purpose of this study is to evaluate the impact of a hospital-based Quality Improvement (QI) program on the use of guideline-recommended oral anticoagulation (OAC) at the time of discharge in hospitalized patients with atrial fibrillation (AF) who are at risk for ischemic stroke. Specifically, the study will determine whether the intervention (QI program elements), compared to Usual Care, results in a greater increase in the proportion of patients with AF at risk for ischemic stroke who are appropriately treated with OAC at the time of discharge. Multidisciplinary Quality improvement teams will be formed in PREMIER hospitals that are randomized to the QI program arm during the Preparatory Phase. These QI teams will include at a minimum a principal investigator (PI) and a study coordinator.

A Premier implementation team will work closely with the study teams that are participating in the QI program arm to ensure completion of all requirements and activities associated with the various phases of the QI program.

The primary data source for the study will be the Premier Healthcare Database (PHD), which is a statistically de-identified HIPAA compliant database used for observational studies and retrospective research.

Condition: Hospitalized patients with AFib with a CHA_2DS_2-VASc score ≥2 points

Study type: non-interventional

Study design: cluster randomized study

Official title: Quantify Use of ANTicoagUlation to improve Management of AF (QUANTUM AF)

Primary outcome measures: The primary measure will be the use of OAC the day before or the day of discharge. The primary comparison will be the change in the proportion of patients treated with OAC, from baseline to final collection periods.

Secondary outcome measures:

- Rate of readmission to the same hospital
  - All-cause readmissions
  - Stroke-related readmissions
  - CV-related readmissions
  - Bleeding-related readmissions
- The use of OAC at the end of study by hospital characteristics subgroups (ie, patient care mix, infrastructure-bed size, staffing, academic status, location, urban/rural, provider)
- Evaluate which components of the QI program were implemented

Study start date: September 2017

Estimated study completion date: April 2020

Estimated primary completion date: March 2020
Groups/cohorts:

Assigned interventions: Hospital sites will be randomized to (1) receive the Quality Improvement (QI) program elements or to (2) continue with usual care in treatment of patients with Afib. QI program elements include: Webinars, Case Studies, Ask the Expert sessions, Expert Panel sessions, Coaching Calls with SMEs and an Online Community/Toolkit.

Eligibility: A total of 150 hospitals (~75 hospitals per arm) will participate in this study. The study will be conducted in eligible hospitals that are a part of the Premier network using QualityAdvisor™ and submit data to the PHD.

I/E criteria:

Inclusion criteria for patient admission towards primary outcome measure:

- Inpatient hospitalization
- Patient age ≥40 years at the time of hospitalization.
- Primary or secondary discharge International Classification of Diseases (ICD)-9/10 diagnosis code for AF persistent (I48.1), chronic (I48.2), or unspecified (427.31, I48.91)
- Proxied CHA_2DS_2-VASC score ≥2 using ICD-9 diagnosis scoring algorithm developed previously (Navar-Boggan 2015) The scoring algorithm will be expanded to include ICD-10 codes.
- Discharged to home, skilled nursing facility, inpatient rehabilitation, or nursing home

Exclusion Criteria for patient admission towards primary outcome measure:

- Presence of artificial mechanical heart valve by ICD-9/10 diagnosis or procedure code during comorbid identification period or current hospitalization.
- Surgical procedure during hospitalization for open heart surgery, brain, or spine.
- Intravenous heparin given on the day of discharge without warfarin/OAC, antiplatelet therapies, and/or aspirin
- History of left atrial appendage occlusion, including the Watchman device
- Any in-hospital (current hospitalization) bleeding identified by ICD-9/10 diagnosis codes.