Feasibility of screening electronic health records to identify participants for a multi-center clinical effectiveness trial in COPD


BACKGROUND

The collection of eligible participants is one of the most challenging aspects of conducting clinical trials. There is increasing interest in leveraging electronic health records (EHRs) to identify patients eligible for clinical trials. RELIANCE is a clinical effectiveness trial in COPD comparing the effects of chronic azithromycin on exacerbation risk and lung function in patients with COPD. The ability to identify eligible patients from the EHR is critical to the success of the trial.

OBJECTIVE

Determine if EHRs could be used to identify patients who may be eligible for the RELIANCE trial.

METHODS

We conducted a 1-year period of planning to determine if the proposed study was feasible. A computerized algorithm was developed to identify patients ≥40 years of age in the EHRs. Site investigators at 33 clinical sites queried their EHR systems to identify patients ≥40 years of age in two strata:

1. **Inpatient stratum**: identified for COPD exacerbation events using ICD-9 or ICD-10 coding systems employed by the Centers for Medicare and Medicaid Services (CMS) Hospital Readmissions Reduction Program; OR 10 billing codes employed by the Centers for Medicare and Medicaid Services (CMS) to identify a hospitalization for COPD. Outpatient encounter with an ICD-9 or -10 diagnosis code of COPD.

In each stratum, site investigators conducted a manual review of EHR records for no. 30 patients (random sample of N=15 patients in inpatient stratum, and random sample of N=15 patients in outpatient stratum). Site investigators recorded the adequacy of the information in the EHR to determine if the patient met each of the following eligibility criteria:

1. **Age ≥ 40 years**
2. **Documented smoking exposure**
3. **Diagnosis of severe COPD with chronic bronchitis**
4. **Current or past smoker with ≥ 10 pack-years**
5. **Presence of long-acting bronchodilator with or without inhaled corticosteroid prescription**
6. **Prescribed a long-acting bronchodilator with or without inhaled corticosteroid**
7. **Not currently prescribed long-term azithromycin or roflumilast**
8. **No contraindications to azithromycin or roflumilast**
9. **Not pregnant**

RESULTS

There were N=104,097 and 160,290 encounters in the inpatient and outpatient strata, respectively.

1. **Inpatient stratum**: 10% (10,409) of inpatient encounters were reviewed (4,955 patients in each stratum).
2. **Outpatient stratum**:
   - 10% (16,029) of outpatient encounters were reviewed (8,014 patients in each stratum).

The proportion of patients who were eligible based on the inpatient stratum (27%, 95% CI 19 to 40%) was similar to the outpatient stratum (26%, 95% CI 19 to 31%).

DISCUSSION

These results are significant as the information content of EHRs to support the determination of eligibility for multi-center clinical effectiveness trials is insufficient in 20 to 40% of patients with COPD to support screening activities for a multi-center clinical effectiveness trial comparing roflumilast and azithromycin therapy.