

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

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### BACKGROUND

Recruitment 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 vs. roflumilast on the risk of death or hospitalization (RELIANCE trial, HSRP20162204).

### 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 prepared to initiate recruitment at all sites. As part of the planning activities, site investigators at 33 clinical sites queried their data systems to identify patients  $\geq 40$  years in two strata:

- Inpatient stratum:** hospitalized for a COPD exacerbation, using ICD-9 or ICD-10 billing codes employed by the Centers for Medicare and Medicaid Services (CMS) Hospital Readmissions Reduction Program; OR
- Outpatient stratum:** 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 N=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:

- Age  $\geq 40$  years
- English or Spanish speaking
- Diagnosis of severe COPD with chronic bronchitis
- Current or past smoker with  $\geq 10$  pack-years
- Hospitalization for a COPD exacerbation in the past 12 months
- Prescribed a long-acting bronchodilator with or without inhaled corticosteroid
- Not currently prescribed long term azithromycin or roflumilast
- No contraindication to azithromycin or roflumilast
- Not pregnant

### RESULTS

- There were N=104,097 and 160,290 encounters in the inpatient and outpatient stratum, respectively.
- EHR records in 990 patients were reviewed (495 in each stratum).
- The proportion of patients who were eligible was higher in the inpatient stratum (36%, 95% CI 27 to 45%) vs. outpatient stratum (7%, 95% CI 5 to 11%); Figures 1 and 2.
- The proportion of patients whose eligibility could not be determined (i.e., unable to assess 1 or more eligibility criteria) was similar in the inpatient stratum (28%, 95% CI 19 to 40%) and outpatient stratum (27%, 95% CI 19 to 37%); Figures 1 and 2.
- The eligibility criteria most difficult to evaluate were (Figure 3):
  - COPD with chronic bronchitis
  - Smoking  $\geq 10$  pack years; and
  - Hospitalization for COPD exacerbation past 12 months

### DISCUSSION

- There are significant gaps in the information content of EHRs to support the identification of patients eligible for the RELIANCE trial.
- As eligibility may vary over time, site investigators will need to complement EHR review with patient interviews to confirm eligibility.

# Documentation in electronic health records 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.

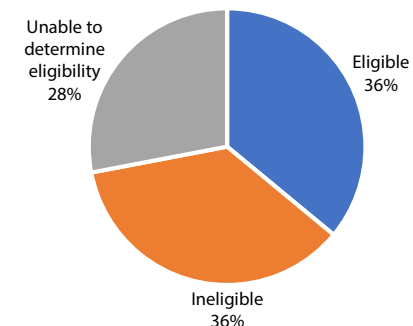


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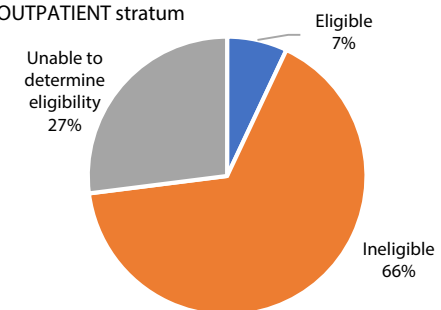


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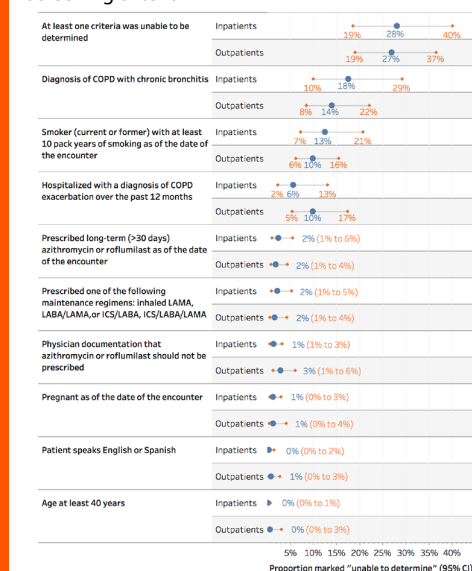
**Figure 1:** Results of chart audit across all sites for INPATIENT stratum



**Figure 2:** Results of chart audit across all sites for OUTPATIENT stratum



**Figure 3:** Eligibility unable to be determined per screening criteria



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