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Demonstrating the Generalizability of Claims Based Studies

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INTRODUCTION

- Evaluating the patient journey necessitates multiple data sources, including patient reported outcomes (PRO) and administrative claims data.
- These data are best understood when collected, deterministically linked, and analyzed for a patient cohort.
- Challenges in that process, such as time, cost, and patient availability sometimes require researchers to rely on the underlying assumption that cohort data are generalizable to the populations they represent.

OBJECTIVE

The purpose of this study was to compare characteristics of a claims-based patient cohort from the Optum Research Database (ORD), identified via protocol requirements from a previously conducted claims-linked PRO study, to the characteristics of patients in that PRO study, thus validating the generalizability of the broader claims-based cohort.

METHODS

- Inclusion/exclusion criteria were used from previously conducted claims-linked PRO study of commercial patients with asthma (N=428) to identify the larger Cohort sample (N=29,094).
  - Inclusion criteria:
    - Age 18 and older
    - Evidence of asthma during the 12-month identification period; evidence will be defined as ≥1 diagnosis code for asthma.
    - Have ≥2 pharmacy claims for FDC ICS/LABA labelled for use with asthma (Advair Diskus, Advair HFA, AirDuo Resplick, Breo Ellipta, Dulera, Symbicort) during the 12-month identification period with ≥1 pharmacy claims for a combination ICS/LABA during the most recent 6 months of the identification period.
    - 12 months of continuous enrollment in a large commercial U.S. health plan affiliated with Optum
  - Exclusion criteria:
    - Evidence of COPD during the 12-month identification period defined as ≥1 ICD-10-CM diagnosis code for COPD in any position on a medical claim (Figure 2).
    - Evidence of cystic fibrosis during the 12-month identification period; evidence will be defined as ≥1 diagnosis codes for cystic fibrosis.
- Descriptive analyses, independent t-tests, and Chi-square tests were used for comparison of results.
- Outcome variables included healthcare resource utilization (HCRU) and asthma exacerbations.

RESULTS

Demographics, comorbidities, and adherence in baseline:

- Participants in the PRO study were older than those identified in the Cohort sample and more likely to be female (Table 1).
- Charlson Comorbidity Index (CCI) was consistent across both groups (Table 1).
- Asthma-related allergies were higher in the PRO study, and medication possession ratio, or MPR, and proportion of days covered, or PDC (measures of adherence), were higher in the PRO study (Table 1).

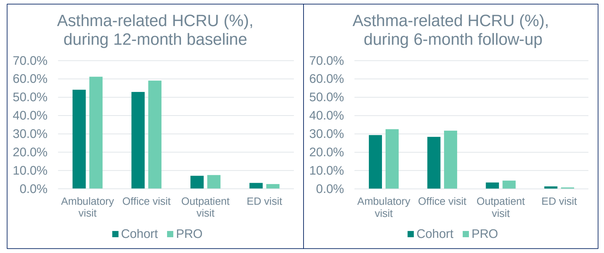
Table 1. Demographics, Characteristics, and Medication Adherence of Study Population for both Cohort and PRO for 12-month baseline period

		Cohort N=29,094	PRO N=428	p-value
Age (years)	mean	47.1	49.8	**<0.001**
	SD	13.1	12.0	
Gender				
Female	n	16,165	286	
	%	55.6	66.8	**<0.001**
CCI score	mean	1.2	1.2	
	SD	0.9	0.8	1.000
Selected comorbidities				
Asthma-related allergies	n	13,356	221	
	%	45.9	51.6	**0.018**
URTI	n	6,386	91	
	%	22.0	21.3	0.733
Allergies with URTI	n	5,014	89	
	%	17.2	20.8	0.053
Anxiety	n	5,743	77	
	%	19.7	18	0.367
Depression	n	4,708	70	
	%	16.2	16.4	0.923
Pneumonia	n	767	14	
	%	2.6	3.3	0.417
SABA use	n	19,601	271	
	%	67.4	63.3	0.076
SABA cannisters				
> 6 during baseline	n	3,208	42	
	%	11.0	9.8	0.426
Maintenance OCS use	n	734	14	
	%	2.5	3.3	0.328
Adherence to FDC ICS/LABA therapy				
MPR >= 0.8	n	10,667	181	
	%	36.7	42.9	**0.017**
MPR >= 0.5	n	19,909	314	
	%	68.4	74.4	**0.029**
PDC for FDC ICS/LABA	mean	0.50	0.54	
	SD	0.24	0.24	**<0.001**
PDC categories				
>= 0.80	n	4,574	81	
	%	15.7	18.9	0.071
>= 0.50	n	13,012	225	
	%	44.7	52.6	**0.001**

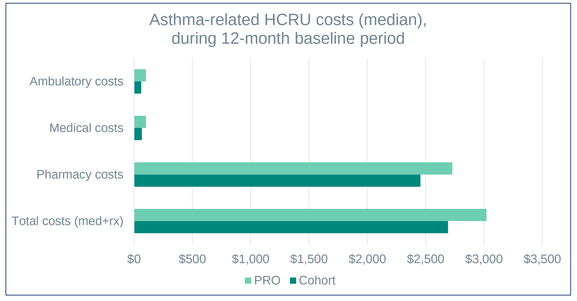
Healthcare utilization:

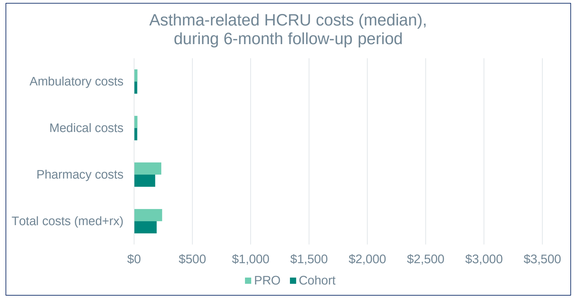
- The PRO study had higher utilization and total cost at baseline (Figures 1a & 2a), but the differences did not remain at follow up (Figures 1b & 2b).

Figures 1a-b. Asthma-related HCRU between Cohort and PRO, for 12-month baseline and 6-month follow-up periods



Figures 2a-b. Asthma-related HCRU costs between Cohort and PRO, for 12-month baseline and 6-month follow-up periods

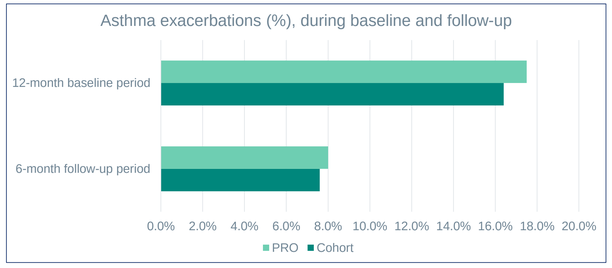




Asthma exacerbations:

- There were no differences in the main outcome variable of asthma exacerbations between the two groups in the baseline (p=.5) or follow-up period (p=.8). (Figure 3).

Figure 3. Asthma exacerbations between Cohort and PRO, for 12-month baseline and 6-month follow-up periods



LIMITATIONS

- This study assumes generalizability of patients who are survey respondents versus non-respondents.
- Large administrative claims samples needs to be used to assume the generalizability of these samples.

CONCLUSIONS

- Although small demographic differences in study participants between a claims-linked PRO sample and larger claims-based cohort sample were found, there were no meaningful differences in the study outcomes.
- These differences reflect those most likely to complete surveys and can be adjusted for in future analyses.
- Ideally, claims data should be deterministically linked for optimal results, this study demonstrates that a larger claims-based sample, from a broad administrative claims database such as ORD, can be a generalizable source of outcomes data when resources are limited.

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