

Assessment Of Us Electronic Medical Records To Guide Feasibility And Design Of The Novelty Study

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Rationale

Since asthma and chronic obstructive pulmonary disease (COPD) have often been viewed as distinct diseases, past biomarker and pharmacotherapy studies have frequently focused on each disease separately, thereby limiting the possibility of identifying the overlapping biological mechanisms between them. NOVELTY (a NOVEL observational longiTudinal studY on patients with asthma and/or COPD) is a prospective, global, cohort study enrolling ~15,000 patients aged ≥12 years with a diagnosis or suspected diagnosis of asthma and/or COPD. NOVELTY aims to describe patient characteristics, treatment patterns, and illness burden over time in clinical practice, and to use biomarkers and clinical parameters to identify phenotypes and endotypes associated with differential outcomes. Electronic medical records (EMRs) were analyzed to understand the potential US patient population for NOVELTY, and assess EMRs as a data source for such research.

Methods

EMR data were collected from four healthcare systems in the Anolinx eResearch Network (A-EMR 1-4; Table), and from the QuintilesIMS US EMR database (IMS EMR). Patients with asthma, COPD or both diagnoses were identified using the International Classification of Diseases-9. Disease severity was classified using treatment- and/or lung function-based algorithms. EMR variable coverage was evaluated over a 12-month period.

Results

EMRs from 654,122 patients with asthma, 735,453 with COPD, and 83,857 with both diagnoses were identified. Asthma severity was classified in A-EMR 1, A-EMR 4, and IMS EMR databases: 23.5%, 1.5%, 0.7%, and 0.1% of patients had mild, moderate, severe and very severe asthma, respectively (unclassifiable in 73.8% across the databases). COPD severity was classified in all databases: 26.7%, 12.0%, and 21.9% had mild, moderate and severe/very severe COPD, respectively (unclassifiable in 39.3% across the databases). In the selected EMRs, many respiratory-relevant variables were infrequently recorded, or were not in searchable formats (Table). Some variables (e.g. exacerbations) may have had low percentages due to low incidence. Patient-reported outcomes (PROs) and symptom data were not documented.

Table. EMR completeness: patients (%) with ≥1 data point for selected variables over a 12-month period*

	A-EMR 1		A-EMR 2		A-EMR 3		A-EMR 4		IMS EMR	
Scope of database	>750 physicians		>1,700 hospitals, clinics, and other facilities		>2,500 physicians		~50 private practices, outpatients/ambulatory clinics only		>40,000 physicians	
Variable	Asthma	COPD	Asthma	COPD	Asthma	COPD	Asthma	COPD	Asthma	COPD
Age/sex	100	100	100	100	100	100	100	100	100	100
BMI	97	97	90	90	94	95	100	100	77	80
Smoking status	98	97	88	88	90	92	100	100	0*	0*
Exacerbations	38	NR	23	NR	36	NR	32	NR	10	11
Prescriptions	73	66	>75	>75	27	69	100	100	44	45
Allergy history	100	100	~90	~90	97	98	>80	>80	NR	NR
Blood eosinophils	59	70	>70	>70	41	55	>60	>60	11	11
FEV ₁	*	*	*	17	*	*	*	*	NR	NR
FVC	*	*	*	11	*	*	*	*	NR	NR
PEF	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Chest X-ray	36	54	>35	>35	27	45	~10	~10	NR	NR
Hospitalization	22	34	21	21	20	36	~10	~10	NR	NR

*Data recorded in EMRs in unstructured format, unable to be collected at a system-wide level for this analysis. BMI, body mass index; COPD, chronic obstructive pulmonary disease; EMR, electronic medical record; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; NR, not recorded; PEF, peak expiratory flow.

Conclusions

EMR analysis allowed assessment of US patient numbers potentially eligible for NOVELTY. In the selected EMRs, disease severity was unclassifiable for many patients, suggesting that treatment or lung function data were not collected, or not readily retrievable from EMRs. Several key variables for airways disease (e.g. lung function and PRO/symptoms) were not readily available with sufficient completeness and frequency over time. Primary data collection for NOVELTY will therefore use electronic case report forms, with the aim to have EMRs provide supplementary data.

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