

APEX COPD, USA Primary Care Registry to change COPD outcomes

Kaplan A^{1,2}, Kocks JWH^{2,3}, Yawn B^{5,6}, Pace W^{7,8}, Make B⁹, Fox C^{7,10}, Skolnik N^{11,12}, Han M¹³, Aranda A¹⁴, Tafur C¹⁵, Mahle C¹⁵, Edwards C⁴, Carter V^{2,4}, Gopalan G¹⁵, Price DB^{2,4,16}

¹Family Physician Airways Group of Canada, Stouffville, Ontario; ²Observational and Pragmatic Research Institute, Singapore; ³General Practitioners Research Institute, Groningen, Netherlands; ⁴Optimum Patient Care, Cambridge, UK; ⁵University of Minnesota, Minneapolis, USA; ⁶COPD Foundation, Washington DC, USA; ⁷DARTNet Institute, Aroua, USA; ⁸University of Colorado, Denver, USA; ⁹Department of Medicine, National Jewish Health, Denver, CO, USA; ¹⁰University at Buffalo, Buffalo, NY, USA; ¹¹Thomas Jefferson University, Jenkintown, PA, USA; ¹²Abington Jefferson Health, Jenkintown, PA, USA; ¹³University of Michigan, Ann Arbor, MI, USA; ¹⁴Hospital Auxilio Mutuo, San Juan, Puerto Rico; ¹⁵Boehringer Ingelheim, Ridgefield, CT, USA; ¹⁶University of Aberdeen, Aberdeen, UK

Introduction

- There continue to be treatment gaps in community management of COPD. While continuing medical education can help reduce these gaps, changing patient behavior is key for improvement¹, and this happens best when patients are involved in their own care.
- APEX COPD (Advancing the Patient Experience in COPD) aims to improve primary care for COPD patients by bringing together electronic medical records (EMR) with Patient Reported Information & Outcomes and presenting this to clinicians and patients in a structured and clinically relevant format at the point of care.
- This will be achieved using modern technology, including Fast Healthcare Interoperability Resource (FHIR), electronic patient surveys, and standardized data collection, and will be guided by a network of COPD clinicians in primary and specialist care.

Methods

Operational Model

Delivery of the registry will occur in partnership with the DARTNet Institute (Colorado, USA) and will include 5 essential elements:

- 1. Primary care network:** A network of engaged Primary Care Clinicians and their COPD patients.
- 2. EMR:** Standardized recording of core data, to be extended/improved over the course of the registry.
- 3. Patient Reported Information & Outcomes:** Information collected via patient survey, guiding point of care consultations.
- 4. Research Database:** Integrated EMR and Patient Reported Information & Outcomes data facilitating data-driven improvements to COPD patient care.
- 5. Clinical Decision Support System (CDSS):** Evidence based Clinical Decision Support (CDS) guiding clinical care & data collection will be developed as a limited exploratory aspect of the initiative to be piloted at key sites.

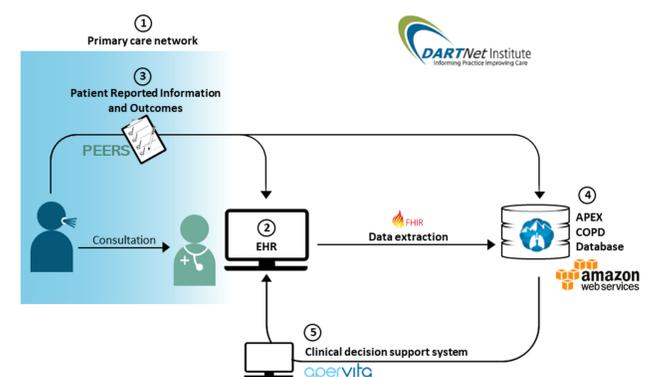


Figure 1 | APEX COPD operational overview.

Patient Population

APEX COPD will collect EMR and Patient Reported Information & Outcomes data from 3,000+ COPD patients across the USA over a 4-year period (2019-2022).

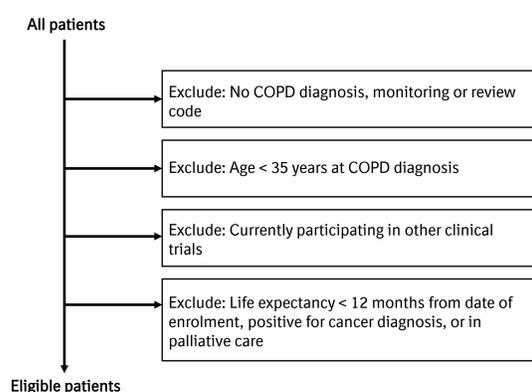


Figure 2 | Patient eligibility for inclusion in the APEX COPD registry.

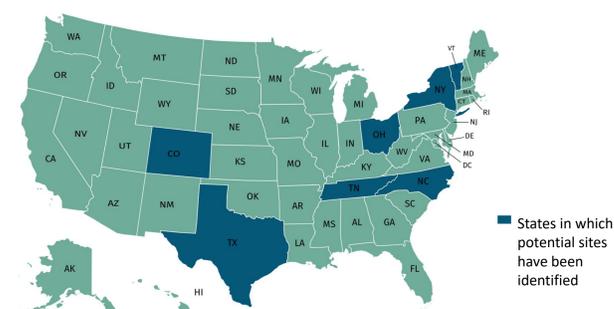


Figure 3 | Patients will be engaged from a number of different sites around the US. Potential sites have been identified in Colorado, Texas, North Carolina, Tennessee, Vermont, New York and Ohio. Sites range from large Safety Net Integrated Delivery Systems, to smaller private clinics. Efforts will be focused on sites with well known EMR systems such as Epic, Cerner and Athena.

Data collection

A panel of 14 COPD experts in primary and specialist care from the US and internationally have come together to define which data are clinically relevant to collect into the registry from EMR, by Patient Reported Information & Outcomes, and at consultation. This process is being completed using a Delphi method; a process of iterative and anonymous voting which assumes that a group decision is more valid than a decision made by an individual².

Variables under consideration include:

- **Patient demographics.**
- **Medical history and symptoms** (COPD relevant) including prior exacerbations, exposure, and comorbidities etc.
- **COPD treatment and management** including medications and side effects (such as those related to steroid exposure and/or biologics), adherence data, where available, vaccinations, referrals, surgery, rehabilitation and other non-pharmacological strategies.
- **Patient-reported information and outcomes** including health status scores (CAT, mMRC), and device satisfaction.
- **Medical test/investigations** including spirometry, electrocardiogram, and biomarkers (blood eosinophils, IgE, and FeNO where possible).

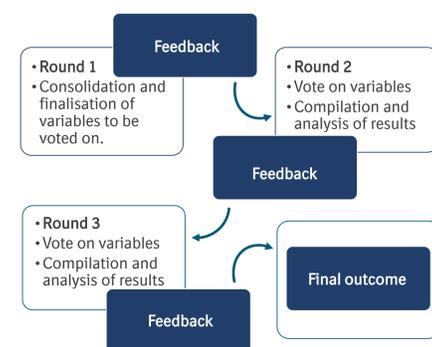


Figure 4 | The Delphi method will constitute of 3 rounds of voting. At the conclusion of each round an independent moderator will summarise the results and present them to all panel members prior to the next round of voting. The final round of voting will bring the panel to a consensus on a group of variables to be collected into the APEX COPD registry. An executive decision will be made on the inclusion of any variables which do not reach a consensus by the end of round 3.

Results

A panel of COPD 14 experts in primary and specialist care voted on 189 clinical COPD variables for collection into the APEX COPD registry. These variables comprehensively covered EMR and Patient Reported Information & Outcomes data collected for COPD. Variables were collated from current COPD guidelines and recommendations including GOLD guidelines, the American Thoracic Society and the European Respiratory Society.

In voting round 1, 6 variables were added bringing the total to 195. After voting round 2, 9 of the 195 variables were excluded from collection into the registry, 170 were confirmed for collection, and 20 require further voting to reach consensus. Of the 170 confirmed variables it was recommended that 115 be collected from EMR, and 16 via Patient Reported Information & Outcomes. No variables were confirmed for collection at by clinicians at consultation. Data sources were not fully agreed on for a number of variables. These are to be voted on in the final round of the Delphi.

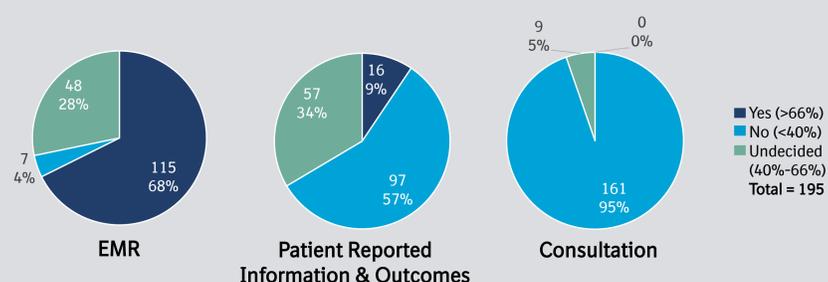


Figure 5 | Results from round 2 of the Delphi voting process for variables to be collected from EMR, via Patient Reported Information & Outcomes, or at the consultation.

Conclusions

- By making the patient a valuable player in the decision making behind their treatment i.e. including them in data collection and feedback, will empower patients to improve the outcomes of their condition, and enable clinicians to provide more informed care for their patients.
- The collective data will form a comprehensive repository in the APEX COPD database for research identifying and solving of key challenges facing primary care clinicians and patients in COPD.

References

1. Zwerink, M. *et al.* Self management for patients with chronic obstructive pulmonary disease. *Cochrane database Syst. Rev.* CD002990 (2014). doi:10.1002/14651858.CD002990.pub3
2. Rowe, G. & Wright, G. Expert Opinions in Forecasting: The Role of the Delphi Technique BT - Principles of Forecasting: A Handbook for Researchers and Practitioners. in (ed. Armstrong, J. S.) 125-144 (Springer US, 2001). doi:10.1007/978-0-306-47630-3_7

Acknowledgements

Funding for this initiative is provided by Optimum Patient Care Global (OPCG) and Boehringer Ingelheim Pharmaceuticals, Inc. (BIP). The authors meet criteria for authorship as recommended by the International Committee of Medical Journal Editors (ICMJE). The authors received no direct compensation related to the development of the manuscript. Formatting assistance was provided by Shaylynn Yu Hui Xin, BSc (Hons) of the Observational Pragmatic Research Institute. Optimum Patient Care Global (OPCG) and Boehringer Ingelheim Pharmaceuticals, Inc. (BIP) were given the opportunity to review the manuscript for medical and scientific accuracy as well as intellectual property considerations.

