Journal of Patient Experience
Volume 10: 1-5

DOI: 10.1177/23743735231151554
journals.sagepub.com/home/jpx
SAGE

The COPD Foundation's COPD360Net Initiative Approach to Patient-Centric Drug Development: A Case Study in Using Patient Surveys to Inform New Treatments for Viral Respiratory Infections

Ruth Tal-Singer, PhD[1], Bruce E Miller, PhD[1], Jean M Rommes, PhD[1], Mark A Luttmann, BS[1], Christophe Demaison, PhD[2], M Bradley Drummond, MD[3], and Cara B Pasquale, MPH[1]

Abstract

Patient-centric drug development is crucial to creating treatments that address unmet patient needs but is often ignored. The COPD Foundation's COPD360Net® includes a multistakeholder approach for operationalizing patient-centric development of treatments where patients, caregivers, scientists, and clinicians review opportunities based on scientific merit, potential to address an unmet need, and feasibility of adoption. COPD360Net deploys large-scale online community surveys to review profiles of potential therapies based on those criteria. This approach was implemented to inform the development of an intranasal spray to prevent viral respiratory infections (VRIs), a major cause of exacerbations in people with chronic lung diseases. Insights included:

1. Of the 376 respondents with COPD surveyed, frequent exacerbators reported strong interest in a new type of antiviral nasal spray to prevent VRI.
2. Patient survey and advisory committee insights demonstrated that a pan antiviral nasal spray has potential high value to both clinicians and patients and informed the COPD360Net decision to partner on its development.
3. Including patient perspectives from the outset can be conducted efficiently by mobilizing an engaged online patient community.

Keywords

COPD, exacerbation, antiviral, viral infection, community survey, patient-centric, drug development, respiratory

Introduction

Patient-centric drug development is crucial to bringing forward treatments that address unmet patient needs and supporting eventual adoption (1). There are few published reports describing the operationalization of this process (2). COPD360Net® is an initiative of the COPD Foundation (COPDF) to accelerate the development and adoption of new or repurposed therapies, digital health tools, and medical devices to treat chronic obstructive pulmonary disease (COPD) and related lung conditions. This report describes the process the COPDF is taking to develop patient-centric approaches to drug development from the outset (3,4).

COPD360Net has created a process that facilitates people with chronic lung conditions, researchers, and other stakeholders working together to review opportunities and prioritize the therapies, digital tools, or medical devices the accelerator network should focus on supporting through strategic partnerships. The focus is on addressing unmet patient needs. The process begins with a potential asset (drug, medical device, or digital tool) being reviewed by the COPD360Net Pipeline Working Group, which is comprised of scientific experts and

[1] COPD Foundation, COPD360Net, Washington DC, USA
[2] ENA Respiratory Pty Ltd, Sydney, Australia
[3] Division of Pulmonary Diseases and Critical Care Medicine, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA

Corresponding Author:
Cara B Pasquale, COPD Foundation, 3300 Ponce de Leon Blvd, Miami, FL 33134, USA.
Email: cpasquale@copdfoundation.org

Table 1. COPD Community Survey Respondent Demographic Information.

Demographic characteristics	Frequency (%)	Demographic characteristics	Frequency (%)
International distribution		Age (years)	
United States	92%	<25	0%
United Kingdom	3%	25-34	0%
Canada	3%	35-44	0%
Europe	1%	45-54	2%
Australia/New Zealand	1%	55-64	23%
Mexico	<1%	65+	74%
India	<1%	I prefer not to answer	1%
United States sistribution[a]		Racial Designation	
New England	10%	White or Caucasian	94%
Middle Atlantic	13%	Black or African American	2%
East North Central	19%	Asian	1%
West North Central	11%	American Indian or Alaska Native	1%
South Atlantic	17%	Native Hawaiian/other Pacific Islander	0%
East South Central	4%	Another race	1%
West South Central	9%	I prefer not to answer	2%
Mountain	7%	Hispanic/Latino?	
Pacific	11%	Yes	97%
		No	2%
		Prefer not to answer	2%

[a]United States Distribution: New England (Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut); Middle Atlantic (New York, New Jersey, Pennsylvania); East North Central (Ohio, Indiana, Illinois, Michigan, Wisconsin); West North Central (Minnesota, Iowa, Missouri, North Dakota, South Dakota, Nebraska, Kansas); South Atlantic (Delaware, Maryland, District of Columbia, Virginia, West Virginia, North Carolina, South Carolina, Georgia, Florida); East South Central (Kentucky, Tennessee, Alabama, Mississippi); West South Central (Arkansas, Louisiana, Oklahoma, Texas); Mountain (Montana, Idaho, Wyoming, Colorado, New Mexico, Arizona, Utah, Nevada); Pacific (Washington, Oregon, California, Alaska, Hawaii).

the COPD Foundation's 360 Community Engagement Committee (360CEnCo), which includes 11 patients and caregivers. 360CEnCo plays a critical role within the Foundation by advising on priorities important to patients and their caregivers ensuring that the interests and safety of patients are always the priority.

If both the scientific and patient/caregiver committees approve moving forward, the asset is brought before the overall COPD360Net Steering Committee that provides the last scientific recommendation on whether to proceed. The final step in the process before creating the development strategy is to conduct a community survey, which is an important tool for gathering and assessing patient perspectives on the asset informing drug development strategies and optimizing therapeutic impact and outcomes.

Herein, we describe the results of this approach when the COPD Foundation was evaluating an opportunity to partner on the development of an intranasal spray to address viral respiratory infections (VRIs). VRIs are associated with increased burden and high healthcare costs (eg, increased doctor, emergency department visits, and hospitalizations) for people with COPD (5–10). There are limited treatment options for preventing or treating VRIs.

Method

To assess patient interest in a potential new anti-viral medicine, the COPDF, via the COPD360Net infrastructure, designed and conducted an online community survey in people with COPD and other chronic lung conditions to inform the engagement of COPD360Net in developing such treatments. The community survey titled, Community Survey on Prevention Options for Viral Lung Infections, was available for 7 consecutive days February 9 and 15, 2022, with prior Institutional Review Board exemption (wcg IRB). The survey was developed with patient input and administered via SurveyMonkey.com with respondents recruited from the COPD Foundation's COPD360social online community, Facebook, LinkedIn, and Instagram postings. Respondents were queried regarding demographics (age, location, race, and chronic disease diagnosis), exacerbation frequency, treatment and hospitalization, healthcare provider preference, nonvaccine antiviral medication use, adherence to recommended vaccinations (flu, pneumonia, and COVID-19), and interest in potential new intranasal, antiviral treatment.

Results

The bulk of the survey responses was received on day 1 (63%) and day 2 (14%) after posting the survey. The results reported here only include those that indicated a COPD diagnosis (n = 342 out of 376 total respondents, or 92%). Respondents were primarily distributed evenly across regions of the United States (92%) and also included respondents from the United Kingdom (3%), Canada (3%),

Europe (1%), Australia/New Zealand (1%), Mexico (<1%), and India (<1%) (Table 1). The respondent demographic was primarily non-Latino Caucasian (94%) and aged >55 years (97%). Respondents with COPD also reported one or more of the following comorbidities: chronic bronchitis (28%), emphysema (56%), alpha-1 antitrypsin deficiency (3%), bronchiectasis (11%), nontuberculous mycobacteria lung disease (3%), and asthma (32%). Within the last 2 years, respondents reported worsening respiratory symptoms that required treatment with oral corticosteroids or antibiotics (82%), emergency department visits (37%), and/or hospital admission (27%). Frequent exacerbators (56% of respondents with COPD) are defined as those experiencing 2 or more symptom-worsening events requiring treatment with oral corticosteroids and/or antibiotics within the previous 2 years.

Respondents' experience with VRI was reported as resulting in an exacerbation that (never, sometimes, often, and always) required cold medicine (11%, 42%, 27%, and 20%), antibiotics and steroids (14%, 45%, 21%, and 20%), hospitalization (63%, 35%, 1%, and 1%), and/or intensive care (88%, 12%, 0%, and 0%), respectively.

Among frequent exacerbators, 84% indicated they typically see a pulmonologist for treatment of their lung condition. Almost all (>92%) were vaccinated for flu, pneumonia, and COVID-19. Medication usage included rescue inhaler (80%), daily inhaler (84%), and/or taking a pill/injection (36%) for their lung condition. Only 17% of frequent exacerbators had ever been prescribed a nonvaccine antiviral medication during flu season; 83% of those would take it if offered again. Respondents were overwhelmingly positive when queried about interest in a potential new type of seasonal antiviral nasal spray prescribed to prevent VRI (not a steroid or vaccine) and reduce flareup/exacerbation (Figure 1A). Frequent exacerbators were very interested (56%-58%) or somewhat interested (26%-27%) in taking this medication (1) twice a week during the winter season to reduce exacerbations and/or (2) for 2 weeks after being exposed to someone with a chest cold to prevent infection. When determining their interest in the potential antiviral medication, frequent exacerbator respondents expressed the most important criteria to be prevention of exacerbation (90%), prevention of VRI (80%), recommendation by their physician (78%), and/or covered by insurance without a co-pay (51%) (Figure 1B).

Discussion

This report highlights the feasibility and value of the patient voice in prioritizing new treatments (patient-centered drug development), an aspect that is oftentimes ignored in clinical development and often focused on market research in a few individuals as well as clinicians' input (11,12). Respondents with COPD that experienced frequent exacerbations reported strong interest in a new type of antiviral nasal spray to prevent VRI if it could truly reduce these events. Through the COPD360Net initiative, this approach was able to quickly gather patient insights and help facilitate rapid decision-making. Gathering this type of information starting de novo would be difficult, slower, and costly.

Limitations

A limitation is that the survey was only administered in English to people with COPD who had access to the online content, limiting the diversity of those who could participate in the community survey. This may have limited the representativeness of the sample, but bilingual Spanish and English speakers were included in the overall in-person committee review process. The survey did not collect information on safety and risk assessment, which are important domains to patients. In the future, the community surveys conducted through the COPD360Net patient-centric process of prioritizing therapies, digital health tools, and devices, aim to include surveys in Spanish and other languages.

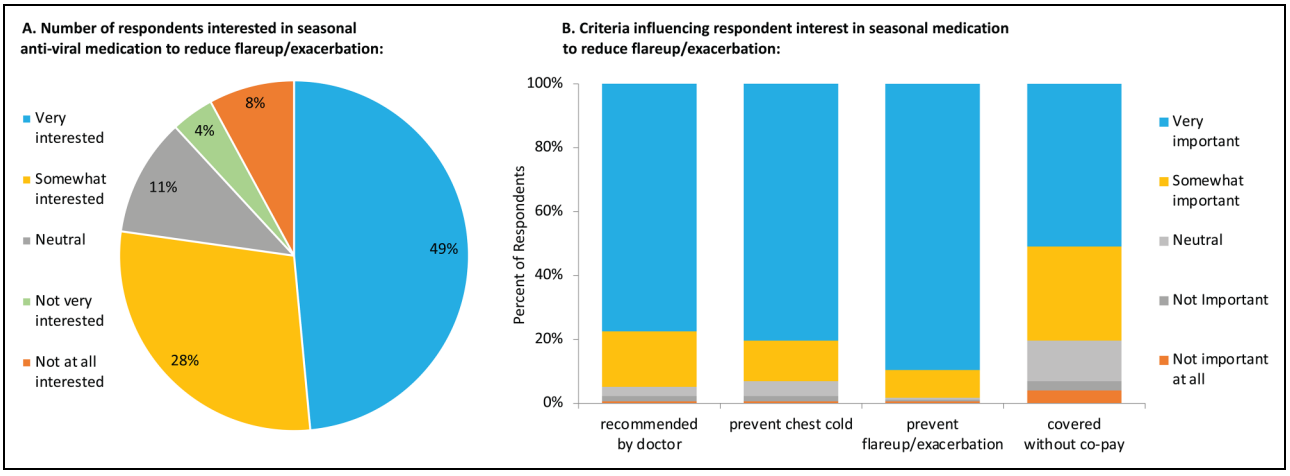

Figure 1. (A) Respondent interest in seasonal anti-viral medication to reduce flareup/exacerbation, (B) Factors influencing respondent choices.

Conclusion

Patient insights demonstrated that there is potential high value to people with COPD for a novel pan antiviral therapy thereby supporting COPD360Net engagement in its development. Utilizing a patient-centered approach by engaging a patient advocacy network to refine a strategy and prioritize investment in development efforts for new therapies, digital tools, and medical devices is possible in an efficient and effective manner. The ability to rapidly obtain patient insights to help inform decision-making should be included in a multi-pronged approach to obtaining input, including large-scale surveys paired with individual-level patient review of the profile of potential therapies. Working with patient advocacy organizations can be an efficient way to obtain the patient perspective to ensure patient-centric drug development.

Author's Note

Ethical approval for Institutional Review Board exemption status under HHS 45 CFR § 46.104(d)(2) for conducting this survey was obtained from wcgIRB (#1-1517328-1; https://www.wcgirb.com/). All procedures in this survey were conducted in accordance with the wcgIRB (#1-1517328-1; https://www.wcgirb.com/) approved protocols. Informed consent for anonymized survey responses to be analyzed by COPD Foundation was acknowledged by respondents' agreement to complete the survey. *Statement on the survey entry page:* "You are not required to provide personal information in your responses to the questions in this survey. Your responses are anonymous and are not linked to your COPD360social or Facebook account. By completing the survey, you acknowledge that the COPD Foundation has your consent to analyze the anonymous responses (data). Your participation in the survey is completely voluntary and you are not required to share any information that could identify you." Ethical approval for Institutional Review Board exemption status under HHS 45 CFR § 46.104(d)(2) for conducting this survey was obtained from wcgIRB (#1-1517328-1; https://www.wcgirb.com/). Stated in the wcgIRB IRB Exemption Determination Letter: WCG IRB's IRB Affairs Department reviewed the study under the Common Rule and applicable guidance. We believe the study is exempt under 45 CFR § 46.104(d)(2), because the research only includes interactions involving educational tests, survey procedures, interview procedures, or observations of public behavior; and any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Drs. Tal-Singer and Miller and Mr Luttmann are former employees and shareholders of GlaxoSmithKline. Dr Tal-Singer is a non-executive director of the ENA Respiratory Board on behalf of the COPD Foundation and holds share options. She also reports personal consulting fees prior to January 2021 from Teva, Immunomet, Vocalis Health, and ENA Respiratory. Dr Rommes is a patient advocate. Dr Demaison holds both shares and share options in ENA Respiratory. Dr Drummond reports research grants from the National Institutes of Health, Department of Defense, PCORI, American Lung Association, Boehringer-Ingelheim, Midmark and Teva unrelated to this work. He reports personal consulting fees from Boehringer-Ingelheim, GlaxoSmithKline, AstraZeneca, Teva, Midmark and Polarean unrelated to this work. Dr Drummond serves as Chair of the COPD360Net Pipeline Working Group.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the ENA Respiratory Pty, Sydney, Australia.

ORCID iDs

Ruth Tal-Singer https://orcid.org/0000-0002-5275-8062
Bruce E Miller https://orcid.org/0000-0003-3904-3182
Mark A Luttmann https://orcid.org/0000-0002-6420-6580
M Bradley Drummond https://orcid.org/0000-0002-6968-4610

References

1. Perfetto EM, Burke L, Oehrlein EM, Epstein RS. Patient-focused drug development: a new direction for collaboration. Med Care. 2015;53:9-17. doi:10.1097/MLR.0000000000000273. PMID: 25494232
2. Geissler J, Ryll B, di Priolo SL, Uhlenhopp M. Improving patient involvement in medicines research and development: a practical roadmap. Ther Innov Regul Sci. 2017;51:612-9. doi:10.1177/2168479017706405
3. Martinez FJ, Agusti A, Celli BR, et al. Treatment trials in young patients with chronic obstructive pulmonary disease and pre-chronic obstructive pulmonary disease patients: time to move forward. Am J Respir Crit Care Med. 2022;205:275-87. doi:10.1164/rccm.202107-1663SO
4. COPDF Digital Health and Therapeutics Accelerator Network (COPD360Net). https://www.copdfoundation.org/Research/COPD360Net-Development-Accelerator/About-COPD360Net.aspx
5. Linden D, Guo-Parke H, Coyle PV, et al. Respiratory viral infection: a potential "missing link" in the pathogenesis of COPD. Eur Respir Rev. 2019;28:180063. doi:10.1183/16000617.0063-2018
6. Porto BN. Insights into the role of the lung virome during respiratory viral infections. Front Immunol. 2022;13:885341. Published 2022 Apr 27. doi:10.3389/fimmu.2022.885341
7. Wedzicha JA. Role of viruses in exacerbations of chronic obstructive pulmonary disease. Proc Am Thorac Soc. 2004;1:115-20. doi:10.1513/pats.2306030
8. Bertino JS. Cost burden of viral respiratory infections: issues for formulary decision makers. Am J Med. 2002;112:42S-9S. doi:10.1016/s0002-9343(01)01063-4
9. Fendrick AM, Monto AS, Nightengale B, Sarnes M. The economic burden of non-influenza-related viral respiratory tract infection in the United States. Arch Intern Med. 2003;163:487-94. doi:10.1001/archinte.163.4.487

10. Rocha-Filho CR, Pereira da Rocha A, Reis FS, et al Economic burden of viral acute respiratory infections in upper-middle-income countries: protocol for A systematic review. medRxiv. 2020. doi: 10.1101/2020.12.14.20248198.
11. U.S. Department of Health and Human Services Food and Drug Administration. Patient-Focused Drug Development: Collecting Comprehensive and Representative Input Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders. 2020; 85 FR 36600. https://www.fda.gov/media/139088/download
12. Chalasani M, Vaidya P, Mullin T. Enhancing the incorporation of the patient's voice in drug development and evaluation. Res Involv Engagem. 2018;4. doi:10.1186/s40900-018-0093-3