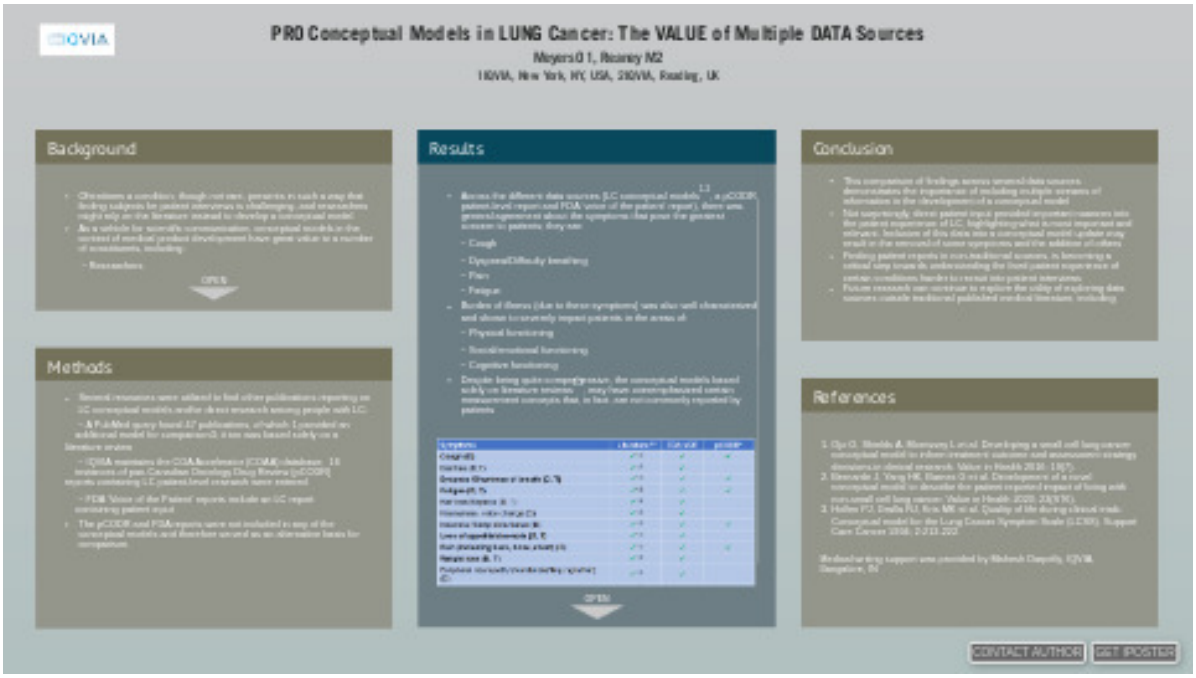
PRO Conceptual Models in LUNG Cancer: The VALUE of Multiple DATA Sources



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PRESENTED AT:

BACKGROUND

- Oftentimes a condition, though not rare, presents in such a way that finding subjects for patient interviews is challenging, and researchers might rely on the literature instead to develop a conceptual model
- As a vehicle for scientific communication, conceptual models in the context of medical product development have great value to a number of constituents, including:
  - Researchers
  - Developers of medical products
  - Regulators, Payers, and Health technology assessors
  - Physicians and other medical care providers
  - Patients and their caregivers
- Conceptual models attempt to describe the burden of disease and its treatment experienced by the patient by listing the components of this experience including signs, symptoms and impacts, showing their relationships and interdependencies
- Ideally these models are developed using data from a variety of primary and secondary sources, including direct elicitation of information about experiences from patients; the optimal approach for conceptual model development includes several key steps:
  - Review the published literature and available clinical guidelines
  - Gain an understanding of the perspective of clinical experts
  - Elicit the patient, and where appropriate, the caregiver perspective
  - Review guidance provided by regulatory agencies, payer authorities, clinical collaborations/committees and patient advocacy organizations
  - Harmonize all of the above data into a scientifically sound model that is appropriate for the context of use
- One such case in point is lung cancer (LC):
  - In recent years, only two publications1,2 in the ISPOR database were devoted to conceptual models of LC; one for Small Cell Lung Cancer (SCLC) and one for Non-Small Cell Lung Cancer (NSCLC). Both are based entirely on published literature, although some of the publications have a patient interview focus.

• Objective

The present study asks the question: How do these literature-based models compare to the results of studies in which patients provided data directly?

METHODS

- Several resources were utilized to find other publications reporting on LC conceptual models and/or direct research among people with LC:

  – A PubMed query found 47 publications, of which 1 provided an additional model for comparison3; it too was based solely on a literature review

  – IQVIA maintains the COA Accelerator (COAA) database; 16 instances of pan-Canadian Oncology Drug Review (pCODR) reports containing LC patient-level research were entered

  – FDA 'Voice of the Patient' reports include an LC report containing patient input

- The pCODR and FDA reports were not included in any of the conceptual models and therefore served as an alternative basis for comparison.

RESULTS

- Across the different data sources (LC conceptual models[1-3], a pCODR patient-level report and FDA 'voice of the patient' report), there was general agreement about the symptoms that pose the greatest concern to patients; they are:
  - Cough
  - Dyspnea/Difficulty breathing
  - Pain
  - Fatigue
- Burden of illness (due to these symptoms) was also well characterized and shown to severely impact patients in the areas of:
  - Physical functioning
  - Social/emotional functioning
  - Cognitive functioning
- Despite being quite comprehensive, the conceptual models based solely on literature reviews[1-3], may have overemphasized certain measurement concepts that, in fact, are not commonly reported by patients

Symptoms	Literature[1-3]	FDA VOP	pCODR*
Cough (D)	✓[1-3]	✓	✓
Diarrhea (D,T)	✓[1,2]	✓	
Dyspnea /Shortness of breath (D, T)	✓[1-3]	✓	✓
Fatigue (D, T)	✓[1-3]	✓	✓
Hair loss/Alopecia (D, T)	✓[1,2]	✓	
Hoarseness, voice change (D)	✓[1,2]	✓	
Insomnia /Sleep disturbance (D)	✓[1,2]	✓	✓
Loss of appetite/Anorexia (D, T)	✓[1-3]	✓	
Pain (including back, bone, chest) (D)	✓[1-3]	✓	✓
Weight loss (D, T)	✓[1,2]	✓	
Peripheral neuropathy (Numbness/tingling in feet) (D)	✓[1,2]	✓	
Weakness/Cachexia (U)	✓[2]	✓	✓
Rash (U)	✓[2]	✓	
Constipation (D)	✓[1,2]		
Hemoptysis (D)	✓[1,3]		
Night sweats/Feeling hot/ sweaty/flushing (D)	✓[1,2]		
Nausea (D, T)	✓[1,2]		
Mouth sores, ulcers (D)	✓[1,2]		
Vomiting (T)	✓[1,2]		
Coughing up blood, phlegm (U)	✓[2]		
Fever (including Febrile neutropenia) (D, T)	✓[1]		
Dehydration (T)	✓[1]		
Cognitive impairment (concentration, memory) (U)	✓[2]		
Swelling (U)	✓[2]		
Acne (U)	✓[2]		
Dry skin (U)	✓[2]		
Itching (U)	✓[2]		
Headache (U)	✓[2]		
Nail loss (U)	✓[2]		
Sore throat (U)	✓[2]		
Difficulty swallowing (U)	✓[2]		
Taste changes (U)	✓[2]		
Dry mouth (U)	✓[2]		
Chest tightness			✓
Increased airborne/allergy triggers			✓

Common ground between the literature-based and patient interview-based reports

Divergence between the literature-based and patient interview-based reports

Findings in only one of the lit-based models, not present in the patient interview based reports

Unique to the patient interview-based reports

Bold text indicated the signs and symptoms which were reportedly most common /most significant

D: Disease related; T: Treatment related; U: Unspecified

* pCODR's Final Clinical Guidance Report for Lorlatinib in NSCLC was used as a recent and representative example of this type of data source

- Therefore, there may be concerns with relying upon conceptual models based solely on literature reviews to make decisions about priority concepts to measure the patient experience
- The areas of divergence between the literature-based models and the patient-interview focused reports include these symptoms, not included in the patient reports:
  - Hemoptysis/Coughing up blood[1,3]
  - Constipation[1,2]
  - Night sweats/flushing[1,2]
  - Nausea and vomiting[1,2]
  - Mouth sores/ulcers[1,2]
- Finally, informed by patient interviews, chest tightness and increased airborne/allergy triggers were included in the pCODR final clinical guidance which were not cited in the literature based models

CONCLUSION

- This comparison of findings across several data sources demonstrates the importance of including multiple streams of information in the development of a conceptual model
- Not surprisingly, direct patient input provided important nuances into the patient experience of LC, highlighting what is most important and relevant. Inclusion of this data into a conceptual model update may result in the removal of some symptoms and the addition of others
- Finding patient reports in non-traditional sources, is becoming a critical step towards understanding the lived patient experience of certain conditions harder to recruit into patient interviews
- Future research can continue to explore the utility of exploring data sources outside traditional published medical literature, including social media

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