Future Opportunities in Lung Precision Medicine Research

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Introduction

Thousands of biomarker tests are either available or under development for lung diseases. In many cases, adoption of these tests into clinical practice is outpacing the generation and evaluation of sufficient data to determine clinical utility and ability to improve health outcomes. There is a need for a systematically organized report that provides guidance on how to understand and evaluate use of biomarker tests for lung diseases. We assembled a diverse group of clinicians and researchers from the American Thoracic Society and leaders from the National Heart, Lung, and Blood Institute with expertise in various aspects of precision medicine to review the current status of biomarker tests in lung diseases.

Experts summarized existing biomarker tests that are available for lung cancer, pulmonary arterial hypertension, idiopathic pulmonary fibrosis, asthma, chronic obstructive pulmonary disease, sepsis, acute respiratory distress syndrome, cystic fibrosis, and other rare lung diseases. The group identified knowledge gaps that future research studies can address to efficiently translate biomarker tests into clinical practice, assess their cost-effectiveness, and ensure they apply to diverse, real-life populations. We found that the status of biomarker tests in lung diseases is highly variable depending on the disease. Nevertheless, biomarker tests in lung diseases show great promise in improving clinical care. To efficiently translate biomarkers into tests used widely in clinical practice, researchers need to address specific clinical unmet needs, secure support for biomarker discovery efforts, conduct analytical and clinical validation studies, ensure tests have clinical utility, and facilitate appropriate adoption into routine clinical practice. Although progress has been made toward implementation of precision medicine for lung diseases in clinical practice in certain settings, additional studies focused on addressing specific unmet clinical needs are required to evaluate the clinical utility of biomarkers; ensure their generalizability to diverse, real-life populations; and determine their cost-effectiveness. Despite a dearth of objective criteria for clinical utility and ability to improve health outcomes, thousands of biomarker tests are available or under development for lung diseases. Research studies are also underway to identify novel biomarkers and seek evidence to support their translation into clinical practice. Health providers routinely use select biomarker-based tests in clinical practice, but some providers lack confidence in deciding when biomarker tests are needed. Researchers performing biomarker-related studies require greater clarity regarding the translation process. Precision medicine is making an impact on patients, health care delivery systems, and research participants in ways that were only imagined fifteen years ago when the human genome was first sequenced.

Discovery of disease-causing and drug-response genetic variants has accelerated, while adoption into clinical medicine has lagged. We define precision medicine and the stakeholder community required to enable its integration into research and health care. We explore the intersection of data science, analytics, and precision medicine in the formation of health systems that carry out research in the context of clinical care and that optimize the tools and information used to deliver improved patient outcomes. We provide examples of real-world impact and conclude with a policy and economic agenda necessary for the adoption of this new paradigm of health care both in the United States and globally.