Cost Drivers of a Hospital Acquired Bacterial Pneumonia and Ventilator Acquired Bacterial Pneumonia (HABP/VABP) Phase Three Clinical Trials

S. Stergiopoulos1, P. Tenaerts2, KA Getz1, C. Brown1, J. Awatin1, S. Calvert2, JA DiMasi1

1. Tufts Center for the Study of Drug Development, Tufts University School of Medicine, Boston, Massachusetts

2. Clinical Trials Transformation Initiative (CTTI), Duke University, Durham, North Carolina

INTRODUCTION

Hospital Acquired Bacterial Pneumonia (HABP) and Ventilator Acquired Bacterial Pneumonia (VABP) are acute infections that occur in hospitalized patients. A hospital stay of 48 hours or more with concurrent patients to potential infections with a variety of gram-positive and gram-negative bacteria.

HABP is defined as an acute infection of the pulmonary parenchyma that is associated with clinical signs and symptoms such as fever, hypoxemia, tachypnea, leukocytosis, purulent respiratory secretions and increased oxygen requirements accompanied by the presence of a new or progressive infiltrate on a chest radiograph in a patient hospitalized for more than 48 hours or developing within 7 days after discharge from a hospital. VABP is defined as an acute infection of the pulmonary parenchyma that is associated with clinical signs and symptoms such as fever, hypoxemia, hypoxia, purulent respiratory secretions and increased oxygen requirements accompanied by the presence of a new or progressive infiltrate on a chest radiograph in a patient receiving mechanical ventilation such as an endotracheal tube for a minimum of 48 hours.

Studies indicate that the prevalence rate of hospital acquired and ventilator associated bacterial pneumonia (HABP/VABP) – conditions that are very challenging and expensive to manage – has been rising. There are many challenges associated with clinical trials targeting these diseases due to the variety of pathogens. HABP/VABP clinical trials are very costly to conduct given protocol complexities and difficulty recruiting and retaining patients. A new study conducted by the Tufts Center for the Study of Drug Development (Tufts CSDD) and the Clinical Trials Transformation Initiative at Duke University (CTTI) evaluates the drivers of HABP/VABP direct and indirect clinical trial costs and identifies opportunities to lower these costs.

METHODS

Tufts CSDD, in collaboration with CTTI developed a comprehensive, detailed mapping of direct and indirect cost elements. Primary cost elements include per-patient direct procedure costs, per-trial and per-site costs.

RESULTS

RESULTS

1. Phase III HABP/VABP clinical trials are $9,000 per-patient more expensive than phase III oncology clinical trials, and $34,000 per-patient more expensive than endocrine studies.

2. Key variables affecting the cost of a typical phase three HABP/VABP clinical trial can be stratified as the number of patients, the number of sites, the cost of screen failure rates, the cost of screen failure rates, and the cost of patient recruitment.

3. Tufts CSDD determined the fully-loaded cost of a HABP/VABP phase III clinical trial with 1,000 patients and 200 global sites to be $115,000 per patient.

LIMITATIONS

1. Assessment of various variables for sensitivity assessment is limited (e.g. procedure costs).

2. Some cost elements are average costs across all therapeutic areas.

3. Assuming that proportion of sites by country is the same as proportion of patients by country.

4. Assuming that site patient percentage is the same for HABP/VABP, oncology, and endocrine trials.

5. Key variables affecting the cost of a typical phase three HABP/VABP clinical trial can be stratified as the number of patients, the number of sites, the cost of screen failure rates, the cost of screen failure rates, and the cost of patient recruitment.

CONCLUSIONS

1. Opportunities to lower the high costs of HABP/VABP clinical trials exist.

2. The cost of screen failure, as well as screen failure rates are the main drivers of cost for a phase III HABP/VABP trial.

3. Future studies are looking to assess best practices for protocol design in order to decrease costs while maintaining scientific rigor.

REFERENCES


ACKNOWLEDGEMENTS

Funding for this manuscript was made available to the Food and Drug Administration (FDA) by Tufts University School of Medicine. The authors are grateful to the staff of the Department of Health and Human Services for their assistance with clinical trials and their comments and suggestions in an organized advisory session held by the FDA in the United States Government.

We thank the FDA, Cambridge Endoscopic Services, Sphero Surgical, Oracle Clinical, and PMS for their help in this study.