Prognostic Test Identifies Infants at High-Risk for Severe Respiratory Infection

VANDERBILT UNIVERSITY
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Summary

Dr. Fernando P. Polack, a leading international researcher in pediatric infectious diseases, has discovered a new prognostic to predict which infants are at high-risk for hospitalization caused by severe **Respiratory Syncytial Virus (RSV)** infections. The test measures a mutation in a single gene, along with a quantifiable environmental factor that confers "susceptibility". The goal is to categorize infants most likely to benefit from preventative care.

Stage of Development

Two prospective studies, involving a total of 1,045 full-term infants, were evaluated to confirm the relationship between RSV infection severity and the genetic and environmental factors.

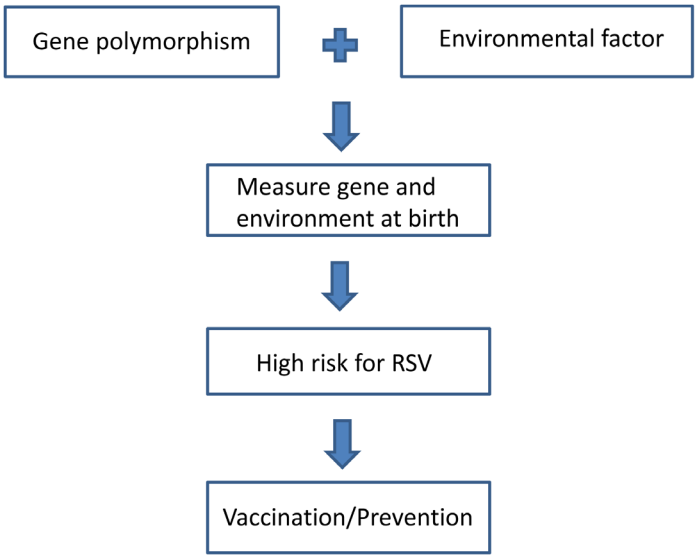

Figure1. A combination of gene polymorphisms and environmental factors can identify infants at risk for severe RSV.

Impact

RSV infections are the leading cause of infant hospitalizations worldwide, affecting 3.4 - 4.0 million infants. In the US, one out of 38 emergency department visits for children under the age of five can be attributed to RSV infection (GlobalData), thereby contributing substantially to healthcare costs. Prophylaxis can protect against RSV infection, but since it is costly, it is only recommended for high risk populations, such as premature infants (representing 1.5% of births). This prognostic test identifies another, much larger, high risk population: full-term infants with the genetic and environmental risk factors. These infants have a 10-fold higher risk of hospitalization caused by RSV, and would benefit from prophylaxis.

Value Proposition

For the Newborn Screening market: Approximately 3.5 million children are born full-term each year. Each state in the US manages a newborn screening program to detect genetic disorders. Optional screening tests are widely available to detect inherited and manageable disorders. A common distribution channel for this test could potentially capture and impact a large segment of the newborn screening market.

For the RSV prophylactic market: Currently, the high cost of RSV prophylaxis precludes its widespread use. However, prophylaxis for this selected high-risk population could change the equation by reducing infant hospitalizations while simultaneously improving infant health.

Technology Details: The gene mutation is present in about 6-10% of the population.

Intellectual Property Status: A U.S. Provisional Patent Application has been filed.

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VU REFERENCE: VU13159

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