Title: A Decision-Tree Approach for a Comprehensive Cost Comparison of Newborn Screening Strategies

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ABSTRACT

Objective: Most research on newborn screening for cystic fibrosis, up to this point, has focused on the benefits of screening vs. non-screening. However, few studies have compared the benefits of various screening strategies. This study compares the costs, outcomes, and system design for the two most prevalent screening strategies in the U.S., IRT/IRT and IRT/DNA.

Study Design: Using a fictional cohort of 100,000 neonates, a two-part, computer-based Monte Carlo simulation program was designed to compare the costs and outcomes for each protocol. The first part of the simulation process resulted in a quantification of outcomes based on a decision tree model for each protocol. The second part of the simulation applied a series of simulated costs to the decision trees, leading to outcome-based cost projections for each protocol. Results were used to analyze the system design of each protocol and identify areas for improvement of each protocol.

Results: A simulation of outcomes for each protocol demonstrated a substantial number of potential missed diagnoses in IRT/IRT vs. IRT/DNA. Nearly 50% of all CF cases may be missed or receive a delayed diagnosis with the IRT/IRT program, compared to 12% in the IRT/DNA protocol. The IRT/IRT system, as defined in this paper, offers a cost savings of nearly \$2 per baby. A breakdown of costs by societal segments (state lab, insurance company, and out-of-pocket/family) demonstrated higher out-of-pocket costs for families in the IRT/IRT system and lower costs to the lab and insurance companies, when compared to

IRT/IRT. Producing similar outcomes to the IRT/DNA system in the IRT/IRT system will increase the overall cost of the program.

Conclusion: The IRT/IRT screening protocol minimizes costs to state labs and insurance companies, but has an increased number of system failures. Outcomes of the IRT/IRT system can be similar to IRT/DNA if the system is re-designed to minimize system errors, but will require an increase in the program.