

COSTS OF IN-HOUSE MUTATIONAL-TESTING AND IMPLICATIONS FOR ECONOMIC EVALUATION: A CASE EXAMPLE OF NON-SMALL CELL LUNG CANCER (NSCLC)

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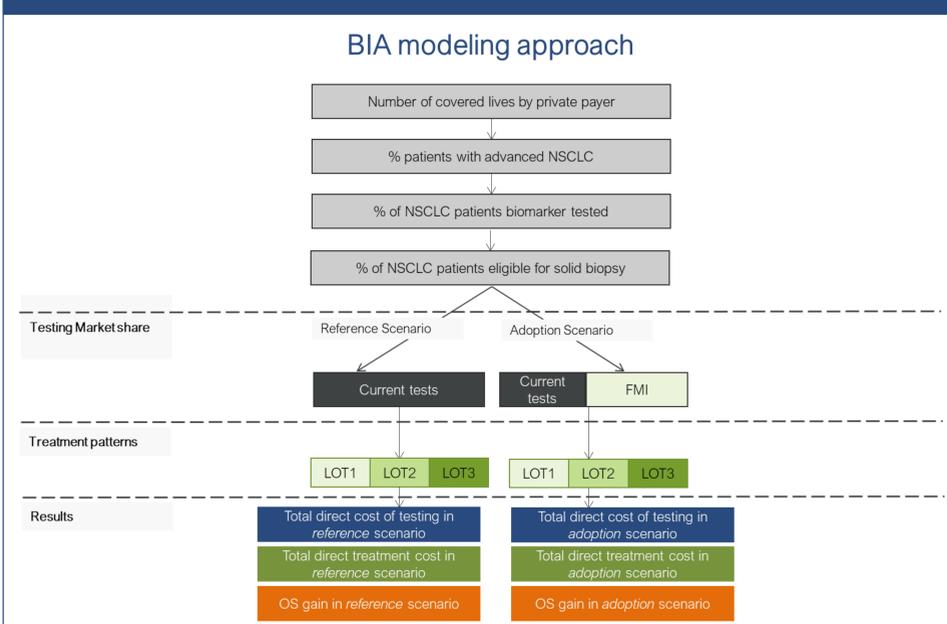
OBJECTIVES

- Genomic profiling in oncology is a key step in determining which patients are eligible for mutation-specific targeted therapies.
- The challenges for economic evaluations of diagnostic testing have been previously described^{1,2} and largely result from the use of modelling techniques that are designed for the analysis of new drugs/therapies.
- To date, when assessing the costs of in-house genomic profiling has, costs typically only include the material costs and do not consider other fixed costs related to the running of a laboratory facility. Conversely, for external tests, the total cost is more transparent and in comprehensively included, by definition.
- Using NSCLC as an example, this study sought to characterize the unique challenges of costing testing services in a Canadian setting and explore their impact on results of economic evaluations.

METHODS

- Structured interviews with Canadian oncologists, pathologists, and laboratory directors were conducted to identify relevant material and non-material costs associated with maintaining and running a laboratory with genomic testing.
 - In British Columbia, sufficient data were available to cost out the capital and operational costs.
- These costs were then incorporated into a previously described model³ (Figure 1) which had been adapted to the Canadian context,⁴ to estimate a more complete cost of in-house testing.
- NSCLC cost-per-test was calculated using overall annual operational costs and relative NSCLC testing volume.
- A health and budget impact model of in-house vs. external commercial profiling services in Canada was utilized to compare the impact of non-material costs on results.

Figure 1. Budget impact model overview



RESULTS

- Based on Canadian laboratory operations for a laboratory conducting 1,300 NSCLC tests per year, total annual non-material costs (Figure 2) included:
 - Equipment maintenance: \$6,842; maintenance for HC-based NGS the most significant contributor to costs (\$6,000)
 - Labour including technicians, administrative and medical staff: \$502,313; salaries for technicians represent the largest cost component (\$240,000)
 - Shipping/reporting and software updates: \$146,050; shipping was the largest cost contributor (\$130,000)

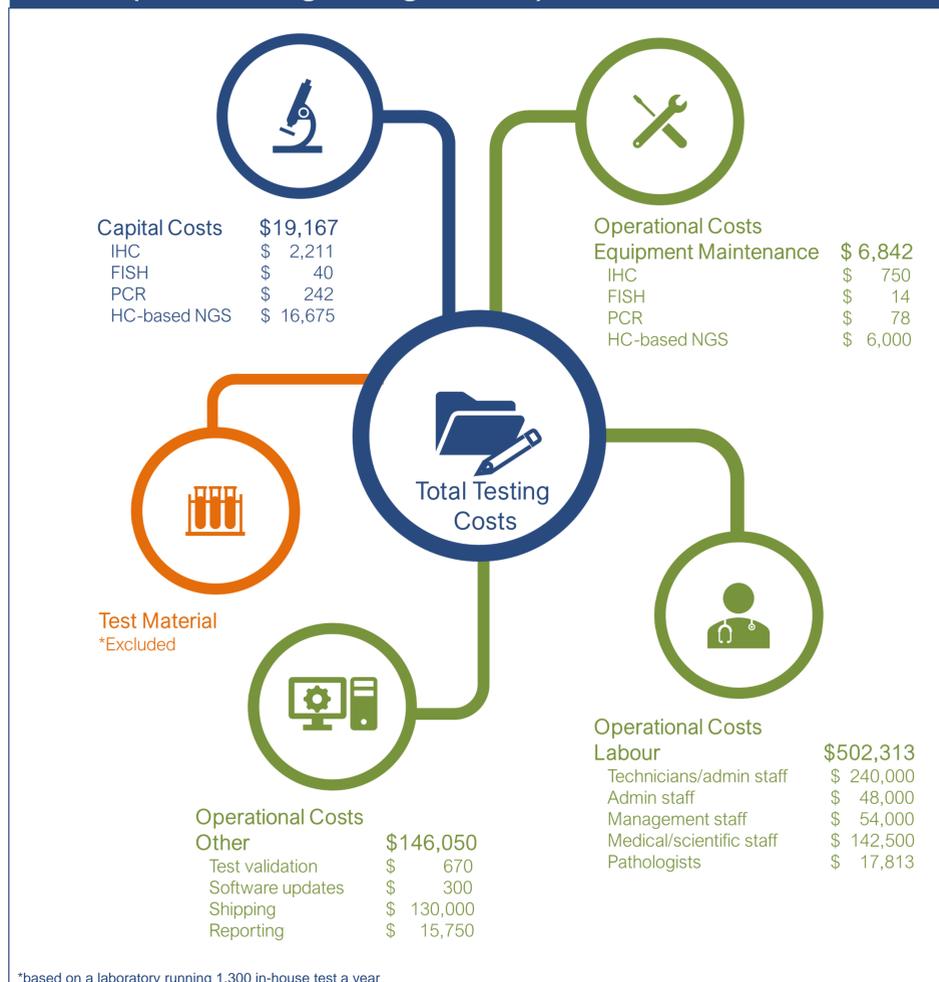
Table 1. Annual capital and operational costs*

	Attributable to NSCLC
Total capital costs**	\$19,167
Total operational costs	\$655,205
Total capital and operational costs	\$674,372.00
Estimated infrastructure cost per test	\$518.75

*based on a laboratory running 1,300 in-house test a year; excluding test materials **estimated out to annual payment

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Figure 2. Annual capital and operational costs attributable to NSCLC (not including testing material)*



*based on a laboratory running 1,300 in-house test a year

Table 2. Testing costs including and not including non-material costs.

	Material costs only	Material costs + non-material costs
Single-gene testing	\$133	\$652
Hotspot panel testing	\$1,400	\$1,919

- When non-material costs were averaged across total tests performed, the combined total was an additional **\$519** per test (Table 1), based on an estimate of 1,300 tests per year.
- In-house testing costs, limited to test materials only, were estimated to be **\$133** for single-gene test and **\$1,400** for a panel (Table 2).
- By accounting for non-material costs, testing costs increased costs to **\$652** for single-gene and **\$1,919** for a panel (Table 2).
- Based on current Canadian testing patterns and anticipated utilization of external testing, inclusion of in-house non-material costs reduced the estimated three-year budget impact of external testing by **12%** compared to the result when only material costs were considered.
- Improved sensitivity of external testing was associated with an additional **0.05** life-years per tested patient.

LIMITATIONS

- This analysis was based on a single centralized testing facility in British Columbia and as infrastructure costs can be highly-specific, future research is needed to assess the cost of testing more broadly across a range of jurisdictions and scenarios.

CONCLUSIONS

- Use of commercial genomic testing has the potential to improve patient outcomes as a result of its optimized quality and overall comprehensiveness.
- When conducting economic evaluation to assess the value of introducing external tests, it is critical that the comprehensive costs of standard testing strategies be measured and incorporated.

ACKNOWLEDGMENTS

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