NATIONAL LUNG CANCER ROUNDTABLE

TURN AROUND TIME (TAT)

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Defining the Problem

- There is a need for large scale utilization of guidelines recommending lung cancer biomarker testing with short TAT for results to guide therapeutic decisions.

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TAT in Lung Cancer Biomarkers
Important Issues

- Guidelines do not endorse specific testing methodologies and algorithms for optimal test utilization.
- Insufficient infrastructure and availability of expanded NGS panel-based testing.
- Reimbursement barriers for NGS testing that prevents wider adaptation.
- Insufficient quality metrics at a local and national level to assess TAT and utilization of biomarker testing.

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TAT in Lung Cancer Biomarkers
Points to Consider

- Choice of platform: single gene vs. multiplex small panel vs. multiplex expanded panel
  - Low cost and faster TAT single gene testing such as ALK IHC, or *ALK/ROS1* FISH, or real time PCR for *EGFR*, *BRAF* vs. NGS.
  - Is there a need for more than one algorithm for testing depending on practice setting and availability of testing platforms?

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	Single gene tests	"Small" (<50 gene) panels	"Large" (50-1000+ gene panel	WES/WGS
Technical considerations	Diverse platforms, can run sequentially	Amplicon NGS, may be dual DNA/RNA assays	Hybrid Capture NGS, single test for mutations, CNVs, fusions	Hybrid Capture, requires paired normal sample
Cost	$ (x # of tests)	$$	$$$	$$$$
Pros	Each test is fast, easy to interpret; gets paid	Fast, good mutation detections, getting better at CNVs, fusions	One stop shopping, can be applied to most tumor types, required for TMB/signatures	Exploratory/ research questions; gold standard for TMB/signatures
Cons	Overall slower than panel, wastes tissue, high "incomplete genotyping" rates	Highly biased, variable utility across tumor types	Weaker fusion detection capabilities relative to RNA testing, slower	Clinically impractical

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  - Low cost and faster TAT single gene testing such as ALK IHC, or *ALK/ROS1* FISH, or real time PCR for *EGFR*, *BRAF* vs. NGS.
  - There is a need for more than one algorithm for testing depending on practice setting and availability of testing platforms.
- Issues specific to type of practice:
  - Large academic centers vs. community-based practice
  - In-house testing vs. send out reference lab testing.
- Proposed algorithm that can be adopted in various practice settings
- Quality metrics for measuring test utilization and TAT at a local (institutional) and national level.

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Barriers to Reflexive/Rapid Testing

- Compliance concerns (Stark law)
- Cost of doing business
  - Lab overhead, reagent costs, labor, equipment maintenance
  - Batching
- Pre-authorization
- Companion diagnostic labels
- Medicare inpatient vs. outpatient status (14 day rule [2018 carve out])

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TAT in Lung Cancer Biomarkers
Areas for Improvement

- Reflex single gene/focused testing has its place but must complement less biased methods for optimal patient care.
- Changes in practice to improve test saturation and TAT require a conducive regulatory/payment environment.
- Tissue and liquid based testing strategies.
- Guidelines endorsing specific workflow algorithms to encourage better adoption into practice.

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