

L. Ferranti, PhD¹, S.K. Padda, MD², N. Singh, MD³, U. Batra, MD⁴, N. K. Warriar, MD⁵, M. Bryl, MD, PhD⁶, B. Budny, PhD⁶, J. Owczarczyk, MD, PhD⁷, M. Zakrewska, MD, PhD^{7,8}, A. Byszek, MDR⁹, Ehrenkranz, PhD¹⁰, H. Massett, PhD¹⁰, M. Yeingst, CFRE¹¹, J. King, PhD¹¹, M. Wynes, PhD¹¹, D. Dilts, PhD¹⁰, K. Kelly, MD¹¹

¹Vanderbilt University, Nashville/TN/USA, ²Fox Chase Cancer Center/Temple University Health System, Philadelphia/PA/USA, ³Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh/IN, ⁴Rajiv Gandhi Cancer Institute and Research Centre, Delhi/IN, ⁵MVR Cancer Centre and Research Institute, Calicut/IN, ⁶Wielkopolska Center of Pulmonology and Thoracic Surgery of Eugenia and Janusz Zeyland, Poznan/PL, ⁷Warmińsko-Mazurskie Centrum Chorób Płuc, Olsztyn/PL, ⁸University of Warmia and Mazury, Olsztyn/PL, ⁹Polska Grupa Raka Płuca, ¹⁰Dilts+Partners, LLC, Nashville/TN/USA, ¹¹IASLC, Denver/CO/USA. **Correspondence:** lori.ferranti@vanderbilt.edu

INTRODUCTION

- IASLC is developing a globally applicable framework for increasing NGS testing to identify actionable genomic alterations (AGA) in NSCLC.
- Despite a trend of increase in NGS testing rates globally, many eligible patients still do not get NGS. Testing rates vary within and between regions both nationally and internationally.
- Comprehensive mapping of NGS testing processes can reveal where, how, and why barriers and gaps exist, why delays occur and consequently can be used to develop frameworks and strategies to address these issues.

METHODS

- Selected countries in 3 regions: Asia (A), Europe (E), and North America (NA).
 - Completed sites: (A) & (E)
 - In process: (NA)
- Using a case-control approach, two sites were selected in each country:
 - One with high NGS testing (A1, E1)
 - One with modest to no NGS testing (A2, E2)

*‘High’ NGS testing was defined as >90% eligible patients tested; ‘modest/no’ defined as <50%. Initial site surveys identified sites’ NGS testing levels.
- At each site, a multi-day on-site visit was completed by experienced systems engineering experts to evaluate and map end-to-end NGS processes using quantitative (e.g., historical NGS rate data) and qualitative (e.g., staff interviews on procedures) methods.
- For each site, a report summarizing observations/recommendations and a process map were created. Sites were then compared to identify similarities and differences.

DISCUSSION AND CONCLUSION

- NGS testing rates are impacted by both site and region factors
- In regions with high *EGFR* or *ALK* rates, an initial single gene testing on tissue approach may be sufficient for treatment decisions.

Future Direction for Research

- IASLC will use this knowledge to build a three-level NGS testing framework (see Fig. 1): external environment, healthcare facility/system, and clinical care.
- The framework will include actionable steps to increase NGS testing rates in eligible patients with NSCLC globally.

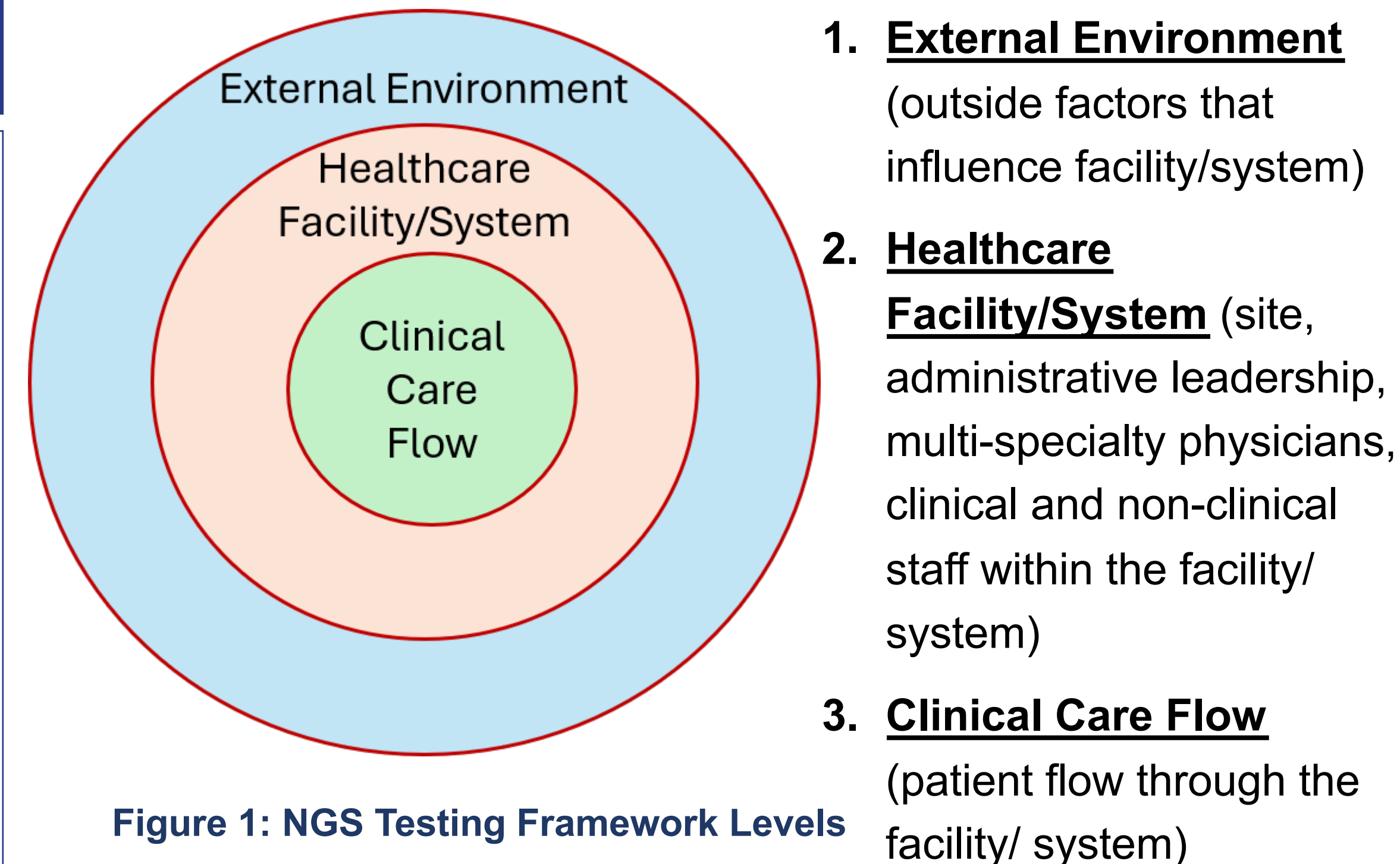


Figure 1: NGS Testing Framework Levels

REFERENCES & ACKNOWLEDGEMENTS

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RESULTS

Finding	Europe & Asia
External Environment Level	
Limited Treatment Availability In-Country	Not all NGS-identified actionable genomic alterations (AGA) have available or reimbursed treatments
Healthcare Facility/System Level	
Repeat Biopsies Needed for Variable Quality External Samples	Variable quality and quantity of tissue blocks from outside facilities frequently require repeat biopsies at all assessed sites
Limited Sample Tracking	No systematic tracking of inadequate biopsy sample rates; reasons and sources of sample inadequacy are not formally measured or monitored
Tissue Biopsy Preferred	Tissue biopsy is strongly preferred at all sites; liquid biopsy is used only as a last resort due to cost and clinical preference
Clinical Care Flow Level	
Patient Profile relatively consistent for Biomarker Testing	Predominantly late-stage (III–IV) or recurrent all histological types of NSCLC; referred from primary care or pulmonary; mix of new and returning patients
Staff providing patient support, including for Biomarker Testing	Nurses and coordinators serve primarily in administrative and patient logistics roles; not involved in medical decision-making
Singe Gene Biomarker Testing Performed, uniquely or part of NGS panel	All sites have implemented single gene biomarker testing as part of routine practice. In the high NGS testing sites the single gene biomarkers were part of the NGS panel.
Multi-disciplinary Team (MDT) Treatment Decision-Making	All sites use MDT for treatment decisions in subset of cases (e.g., tumor board, morning stand-up medical oncologist (MO) meetings, or tiered junior/senior MO review)

Table 1: Region Similarities

Finding	Europe (E1, high NGS testing rate; E2 modest)	Asia (A1, high NGS testing rate, A2 modest)
External Environment Level		
Healthcare Funding Model	Fully government-funded; no direct patient payment permitted	Private/out-of-pocket; ~50–60% uninsured; payment required before services
Repeat Imaging Requirements	CT scans must be ≤28 days old prior to treatment start; if older, scans must be repeated	No equivalent time-constrained imaging validity rule
NGS Cost Mechanism: Reducing Out-of-Pocket to Costs	NGS testing costs covered via government milestone-based reimbursement	Pharmaceutical company coupons subsidize NGS testing (A1: coupons go to patients; A2: coupons go to external lab)
Healthcare Facility/System Level		
NGS Gene Panel Size (highly variable)	E1: 42-gene IVD (<i>In Vitro</i> Diagnostic) panel; E2: No NGS; sequential single-gene only	A1: 34-gene panel (includes potential future AGAs) A2: 12-gene NCCN-guideline panel of current AGAs with available treatments in the country
Hospital Type / Ownership	Public hospitals	Private hospitals
In-House vs. External NGS Testing	E1: In-house E2: NGS not done	A1: In-house A2: External
NGS Turnaround Time (biospecimen to NGS report)	E1: ~33 days E2: NGS not done	A1: ~14 working days (varies due to batching of samples); A2: 14–21 days (including transport time to external lab)
Clinical Care Flow Level		
Patient Access / Scheduling that impacts NGS report timing	Appointment-based system; formal referral required via pathway	Both appointment and walk-ins; no referral required
Single Gene Testing (SGT) Role	E1: only NGS testing, no SGT E2: only SGT, no NGS testing	A1: only NGS testing, no SGT A2: transitioning from SGT to NGS testing *High regional EGFR/ALK rates may make SGT sufficient
Treatment Initiation Timing	Treatment generally withheld pending NGS results; NGS guides treatment initiation	NGS modifies rather than initiates treatment

Table 2: Region Differences