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Optimizing the Precision Oncology Workflow at a Public Safety-Net Cancer Center

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ABSTRACT

Background: Comprehensive tumor molecular profiling using next-generation sequencing (NGS) enables personalized cancer treatment and is standard of care in the management of advanced solid malignancies. Given challenges with efficient implementation of NGS testing in safety-net health care settings, we evaluated the tissue NGS workflow at our facility and investigated the impact of a targeted specimen courier service intervention. Methods: We constructed a NGS workflow process map to identify key stakeholders and potential sources of delays. 26 clinicians were surveyed regarding time spent placing orders, reliance on a process guide sheet, and adherence to key steps in the ordering process. Utilization and process data from 2019-2022 was obtained from our NGS vendor. Time from order placement to result report [Turn Around Time; (TAT)] was the primary process

measure; secondary measures were time from order placement to specimen receipt by the vendor [Order to Specimen (OTS)] and time from specimen receipt to reporting of results [Specimen to Report (STR)]. Medians for TAT, OTS, and STR were compared over 3-month intervals, and pre- and post-courier service implementation. A Root Cause Analysis was conducted to identify additional delays and opportunities for further optimization. Results: Between 2019 and 2022 median TAT was 22 days, with a downward trend in median TAT to 18.5 days at the end of 2022. Median OTS and TAT were significantly improved following courier service introduction (13 vs 7 days and 23 vs. 18.5 days, respectively). STR remained stable throughout the periods of interest. Only 63.6%-72.7% of clinicians reported correctly completing key steps of the ordering workflow possibly contributing to delays in OTS and TAT. Conclusions: We assessed the complex effort of optimizing the NGS testing workflow at a large safety-net health system. Courier service implementation improved OTS and overall TAT. Surveys identified inefficiencies in the provider side of the ordering process. Future opportunities to improve TAT include NGS order integration with electronic medical systems.

INTRODUCTION

Comprehensive tumor molecular profiling using next-generation sequencing (NGS) may enable more personalized cancer treatment and has become standard of care in the management of most patients with advanced solid tumors. Efficient implementation of NGS testing into health care systems can be challenging, especially in safety-net health systems with a high proportion of underserved populations. Our institution is a safety net tertiary referral center in New York City offering comprehensive cancer care services. We use the most commonly ordered, commercially available, NGS test which profiles 324 genes. The vendor advertises a typical result availability of 12 days or less from receipt of specimen.

METHODS

A process map was constructed and identified key stakeholders. These stakeholders were interviewed. A Root Cause Analysis of our NGS tissue testing workflow - consisting of processes related to ordering, pathology processing, and result review was performed to identify key sources of delays.

Surveys were administered to all ordering clinicians including 18 fellows, 6 attending physicians, and 2 nurse practitioners in Medical Oncology. Survey questions included time spent ordering NGS testing, how often clinicians needed to reference an ordering process document for reminders, how consistently key steps in the ordering workflow were completed (e.g., required orders were placed in the EMR, support staff notified of requested testing, financial paperwork was completed), and awareness of financial assistance requirements based on insurance status/payor type.

Utilization and process data from 2019 - 2022 was provided by our NGS Vendor. A clinically meaningful, primary measure of process quality "Turnaround time" (TAT) was selected to represent the time from a clinician deciding to order NGS for a patient (aka when an order was placed in the EMR) until the report was available for clinical use (aka result time). Key secondary measures of process quality were 1) "Order to Specimen" (OTS) defined as the time from order placement in the EMR to specimen receipt by the testing vendor and 2) "Specimen

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to Report" (STR) defined as time from specimen receipt to result availability for clinical decision making (Results available in our NGS Vendor's online portal).

We analyzed the trend in median OTS, STR, and TAT from January 2019 to December 2022. We also assessed the impact on the implementation of a NGS specific courier service implemented in July 2022. To do this, we compared the median OTS and TAT from January 2019 - June 2022 and July 2022 - December 2022.

RESULTS

Figure 1 describes our current NGS workflow. The workflow involves specific inputs from the ordering provider, clinical oncology support team, the department of pathology, and our NGS vendor.

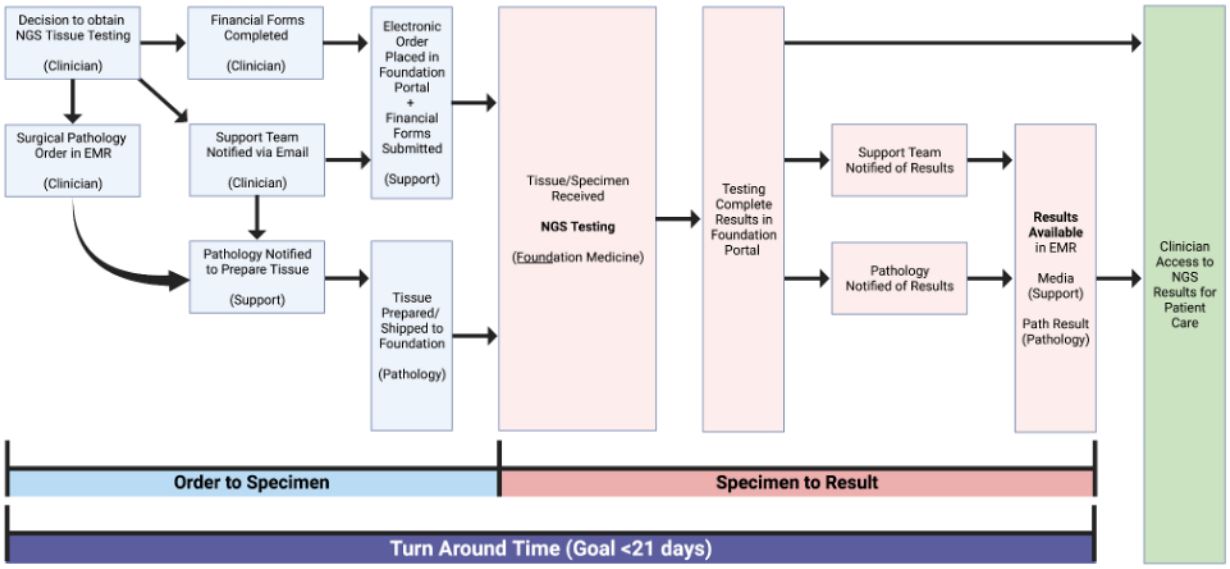

Figure 1: NGS Workflow

The NGS workflow begins with a provider initiated ordering process. This step requires an EMR-based pathology order, completion of requisite financial documentation in paper form, and email notification of the NGS administrative team. Once these steps are complete, the administrative team coordinates with the Pathology department to prepare the necessary pathology samples and send them to our NGS vendor for analysis. Once the analysis is complete, the results are available in the NGS vendor online portal and are scanned into the EMR. The figure also presents the workflow steps in our primary and secondary process measures. TAT includes every step in the workflow described above. OTS includes provider order placement, completion of financial documentation, coordination with the pathology and NGS administrative team, pathology preparation, and shipment. STR includes the testing time at our NGS vendor and result receipt by our institution.

Our workflow demonstrates a process that requires optimal physician adherence to a multifaceted ordering process requiring inputs in the electronic medical record, email-based communication, and paper-based documentation. Furthermore, it requires optimal integration of technology-based ordering mechanisms, the department of pathology, and hospital logistics

to have a properly prepared sample sent to our vendor in a timely manner. Analysis of this workflow reveals two primary sources of inefficiencies, provider sourced inefficiencies and system sourced inefficiencies.

To further assess causes of provider sourced inefficiencies, we distributed surveys that assessed knowledge of the ordering process, adherence to essential ordering process steps, and result review practices. Our surveys results, described in Figure 2, revealed suboptimal adherence to mandatory steps in the ordering process, with complete adherence ranging from 54.5% - 72.7%.

Figure 2A. Responses to frequency in placing Surgical Pathology Order in Electronic Medical Record

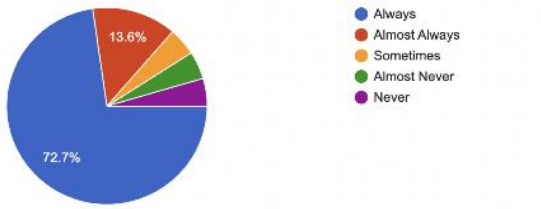

Figure 2B. Responses to frequency in sending mandatory email request to NGS Support Staff

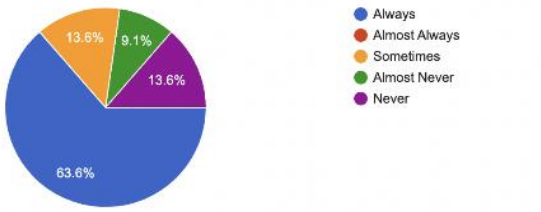

Figure 2C. Responses to frequency in completing mandatory financial assistance paperwork

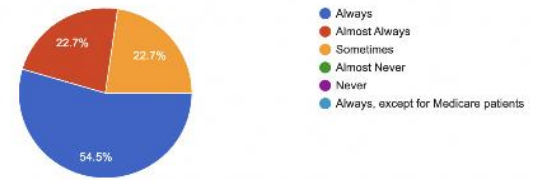

Figure 2: NGS Provider Survey Responses

Pie chart diagrams representing percentage of respondents (N = 22 respondents of 26 surveyed) selecting the options on a Likert scale. 100% compliance to each of these steps is mandatory to begin preparation of pathology samples for NGS testing

2A. Response distribution of respondents when asked if they place the appropriate 'Surgical Pathology' order in the EMR.

2B. Response distribution of respondents when asked if they send the appropriate email communication to the NGS administrative support team.

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2C. Response distribution of respondents when asked if they complete the mandatory financial assistance forms for patients. (Image created with Biorender.com)

NGS Turnaround Time Data

Analysis of our precision oncology process measures revealed an overall downtrend in the median TAT from January 2019 to December 2022. Further insight revealed that this decrease was largely driven by decreases in OTS time, the time of EMR-based NGS order to specimen receipt by the vendor. STR was stable throughout the study period and was within the NGS vendor's goal of 10 days. Based on our analysis, the median TAT in 2019 was 22 days, and this was followed by an increase to 26 days in 2020 and 2021. In 2022, the median turn around decreased to 18.5 by December 2022.

Implementation of NGS Courier Service

As mentioned, the variability in turnaround time was due to variability in the OTS. Our analysis demonstrated that the median STR time was consistently within the vendor's goal of 12 days from 2019-2022. It was 10 days for the years 2019 and 2020, and 9 days for 2021 and 2022. This is due to standardization of the vendor's NGS testing process upon receipt of the specimen. A NGS specific courier service was implemented in July 2022 to reduce the OTS. Prior to the implementation of the courier service, NGS samples would be placed in the centralized pathology shipment queue and a group of samples would be sent together. The courier assisted in procuring the prepared sample from pathology upon completion and promptly shipping it to the vendor via expedited service. Implementation of the courier service resulted in a significant decrease in the OTS time. From January 2019 to June 2022 - the time period prior to courier implementation - the median OTS was 13 days. Following the implementation of the courier service, the median OTS from July 2022 to December 2022 was 7 days. The TAT also demonstrated improvement following courier intervention. The median TAT from January 2019 to June 2022 was 23 days. Following the implementation, the median TAT from July 2022 to December 2022 was 18.5 days.

DISCUSSION

Molecular testing through NGS of tumor DNA has become an essential diagnostic tool for patients with advanced solid tumor malignancies. Identification of targetable mutations have shifted the paradigm of treatment for many advanced cancers. Procurement and processing of NGS testing is essential for optimal patient care because advanced cancers often require prompt treatment to avoid suboptimal outcomes. Delays in NGS testing can result in adverse consequences including initiation of suboptimal therapy, increased patient distress, and increased costs of care. Our study evaluated the efficiency of our NGS testing process through examination of TAT data. Furthermore, it identified delays that are more pronounced in a public safety net hospital setting serving a high proportion of Medicaid and uninsured patients.

This project highlights the value of implementing NGS specific workflow initiatives to address operational bottlenecks (defined as the step with the highest non-work related wait time and highest number of backlogged items). In our workflow we identified the sample shipment queue as a key bottleneck. Here, the implementation of a NGS courier to ameliorate the bottleneck resulted in the improvement of median TAT from 23 to 18.5 days. Our experience is also comparable to the NGS TAT of 16 days observed in the Kaiser Permanente Northern California Group following optimization of their Stage IV Non-Small Cell Lung Cancer (NSCLC)

NGS workflow from 2018 to 2021. Given the limited data available on NGS TAT, this group presents a potential ideal benchmark because it is a fully integrated system with standardized operating protocols and a universally insured patient population.[1,2]

We identified several reasons for delayed TAT, including suboptimal adherence to the complex workflow and a process with numerous handoffs between stakeholders. The number of ordering steps, the different modalities of ordering, and the time taken to complete all these steps were key sources of non-adherence (Figure 2). If any essential steps were missing or incomplete, NGS orders were unable to trigger the pathology preparations for vendor testing. We also found that our process had 5 different handoffs (defined as information or material exchange between individuals or departments). The Kaiser group identified approximately 8 handoffs in their NSCLC NGS workflow prior to intervention, citing this as a significant source of suboptimal TAT. Reduction of handoffs of information and physical materials should be a primary operational improvement objective.[1]

Streamlining order placement is a key opportunity for further NGS workflow optimization. The number of inputs should be reduced from the current multimodal process which includes EMR, paper, email communication, and vendor web-portal data entry to a single, integrated, EMR-based order which directly communicates the request for NGS testing to all relevant parties. Reducing the ordering workflow burden can reduce the risk of non-adherence. The effect of single point EMR ordering was evaluated by the PennChart Genomics Initiative (PGI) at the University of Pennsylvania Health System where an EMR integrated ordering and result review system for genomic data was implemented. Entry of a single EMR order directly transmitted the request to the appropriate laboratory/vendor. Upon completion of testing, results were transmitted directly into the EMR using standardized nomenclature and were visible for clinician use. The impact on time spent on ordering and result review were assessed as primary endpoints. The integrated genomic data EMR workflow revealed a significant reduction in time spent ordering (8 minutes vs. 2 minutes, $p < 0.001$) and the result review process (5 minutes vs. 1 minute. $p<0.001$). This experience demonstrates the reduction in clinician burden that can occur with simplified and EMR-integrated genomic/biomarker workflows.[3] EMR integration represents a future initiative to further optimize our NGS workflow and improve provider adherence and may alleviate additional operational bottlenecks such as an accumulation of unprocessed order requests from providers to pathology.

There are several limitations of this investigation. First, the use of vendor provided data to define the total population of interest may have introduced sampling bias. The vendor is only able to capture data on samples that successfully underwent order placement within their portal. Testing requests that failed to generate a vendor work requisition were not captured in our analysis. Furthermore, for those that did have adequate work requisitions and were included in our analysis, we cannot quantify any lead time delays attributed to repeated provider ordering steps due to errors. TAT and our secondary process measures—OTS and STR—were contingent on samples successfully completing the entire workflow. Of the 497 cases provided by our NGS vendor, complete workflow data was only present on 357, representing the absence of 28% of total cases introducing another potential source of sampling bias. Canceled tests were primarily due to provider-decision, insufficient tissue, or incorrect order placement. Additionally, the delays related to repeat tissue sampling due to

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insufficient tissue samples were outside of the scope of this analysis as they are not reflective of the NGS workflow.

Another limitation is the single institute site of study. Our facility is a tertiary care, safety net hospital in New York City. However, this setting also represents an opportunity to generate knowledge to expand access to NGS testing at similar safety-net facilities. Many metropolitan areas in the United States have at least one operational safety-net hospital or health system. These facilities serve populations predominantly in demographic and socioeconomic categories who are less likely to receive NGS testing, have poorer cancer-related outcomes, and are less represented in both clinical trials and genomic studies.[4, 5, 6, 7] The largest portion of patients by self-identified race at our facility is black (22%). Moreover, most patients within our catchment rely on government insurance programs/Medicaid (45%), or are uninsured (31%).[8, 9] While there is limited data on the impact of payor status on tumor NGS testing access, it has been shown that having Medicare, Medicaid, or no insurance can delay the receipt of germline genetic testing which are considered to be standard of care for many tumor types.[10] Delays in cancer diagnostics is one of many reasons underrepresented minorities, as well as patients on Medicaid, and uninsured patients have suboptimal outcomes and lower overall survival across many cancer types.[5, 6] Historically, safety-net facilities have maintained close affiliation with academic medical centers, and have served as major sites for medical training. Enhanced partnerships between academic institutions and safety net health systems are opportunities to ameliorate service gaps and allow for resource sharing. With the appropriate buy-in from academic partners, NGS testing can be significantly scaled at safety-net affiliates. Understanding the systems of shared resources between academic and safety net health systems and identifying areas of opportunity for capacity building and investment can help ensure timely access to NGS testing for vulnerable communities. These partnerships can allow academic medical centers to fulfill the mission in delivering equitable care for their communities.

In conclusion, this is the first paper to report TAT for NGS testing in a safety-net/underserved setting. Others have demonstrated that simplifying the ordering process through EMR integration of genomic ordering has alleviated provider burden and can potentially improve provider adherence. Furthermore, partnering with commercial NGS vendors to create streamlined financial approval mechanisms, and engaging stakeholders in the department of pathology to develop NGS specific workflows can all reduce clinician burden and optimize NGS TAT.

More studies regarding NGS implementation and workflow optimization, EMR integration, and financial disparities in NGS access are needed, particularly in safety-net care settings to elucidate further challenges and solutions.

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