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Multidisciplinary Workflow Implementation for ctDNA Kit Collection to Decrease Inefficiencies for Patients and Staff: A Quality Improvement Initiative

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Abstract

Background: Circulating tumor DNA testing in the oncologic clinic setting is used to detect residual disease and genetic mutations for targeted therapy options.

Local Problem: This quality initiative was developed to standardize circulating tumor DNA kit (ctDNA kit) collection in a rural academic medical cancer center. The use of third-party ctDNA testing kits within the clinic has increased in the last three years to detect genetic markers for targeted therapy.

Methods: The use of a *plan-do-study-act* framework was utilized to revise the workflow for the ctDNA kit collection process to decrease total collection time and increase staff satisfaction.

Intervention: With key stakeholder support a revised workflow was implemented to address the need for ctDNA kit collection process. Test requisition forms and test kits were relocated within the clinic to improve ease of access.

Results: Staff satisfaction increased from a mean of 1.17 pre-intervention to a mean of 2.7 of post-intervention in those surveyed and total collection time decreased from a mean of 37 to a mean of 19 minutes following implementation.

Conclusion: The global aim to reduce total collection time was met and to increase staff satisfaction, however, the specific aim to decrease total collection to 15 minutes was not met. Future implementation cycles could include contractual development with the kit vendors to ensure proper billing and electronic health record integration to improve access to results.

Keywords: quality initiative, ctDNA, circulating tumor DNA, workflow implementation, process development

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Introduction

Within an oncology outpatient clinic, the use of circulating tumor DNA (ctDNA) kits are used by providers to detect residual disease and genetic marks to aid in the identification of targeted therapy options. A standardized workflow was developed to meet the increasing need, to improve clinic flow and reduce delays. The integration of ctDNA kits allows for the identification of specific mutations within the genome. This knowledge drives treatment based decisions. The ctDNA kits detect residual disease, which may not appear on standard lab tests or imaging. By offering these kits, they bring a more comprehensive level of care for the patients affected by HPV-positive head and neck cancer for disease tracking, lung cancer patients for treatment- based decisions and many more patients treated for thoracic or melanoma cancer types.

Problem Description

This quality initiative occurred within the cancer center clinic embedded in a rural academic medical center. The cancer center serves a significant number of patients at multiple locations with a multitude of hematologic-oncologic diagnoses. The primary cancer center location sees an average of eight- hundred and fifty patients per week, cared for by forty providers and specialized advanced practice practitioners. The microsystem assessment of the cancer center clinic identified multiple processes that would have benefited from standardization. However, the voice of the customer feedback determined that the ctDNA kit collection process could have been more efficient for both staff and patient clinic flow. The lack of a standardized workflow for the kit collection process leads to delays at many clinics service points. The procedure before implementation failed to define roles in the kit collection process, which led to

interruptions starting with the initiation of the collection process. The physical location of the kits, the order process within the electronic health record, test requisition form requirements for each kit type, and laboratory draw orders all contribute to delays in the process. Of the numerous kits and providers who order ctDNA kits, individuals developed to complete the collection process to meet each need in the clinic space.

Available Knowledge

The collection process pre-implementation led to multiple delays for patients and staff, leading to frustration related to delays in collection and rejected samples from kit companies due to incomplete form completion or lab labeling. The ctDNA kit collection workflow pre-implementation involves the provider leaving the patient's room, getting a kit, returning to the room, and obtaining written consent with the patient. Once complete, the provider would walk the patient and the kit to the lab. The patient would be considered a walk-in and drawn when staff was able. The providers used a miscellaneous lab order for the kit and a "research draw" order; the health system absorbed the cost of the misused research draw. The phlebotomist would draw per kit specifications and then contact the clinic nurse to pick up the kit for mailer preparation. Observations identified the most considerable disruptions: the provider leaving the patient's room to retrieve the kit, the incomplete form, and contacting the clinic nurse for kit mailer preparation. The specificity of the topic, initially defined as workflow implementation in outpatient cancer center clinics, was the main search driver in the literature search. The literature search question was, "For patients that require ctDNA testing, what is the effect of implementing a standardized workflow on total collection time and other outcomes?"

Search Methods

The literature review intended to identify references to standardized workflow implementation in outpatient clinics. The databases queried used to search were PubMed and Cumulated Index to Nursing and Allied Health Literature. The search criteria included keywords; workflow implementation, healthcare, and process improvement. Limitations within the literature search were set to date range, publication date no earlier than 2013, peer reviewed journal, randomized, and literature review. Inclusion criteria included multidisciplinary AND oncology clinic AND implement* OR workflow. The asterisk allows for truncations to be searched as well. The search was limited to publications in the English language and those in full text. Forty-nine records were identified in the investigation, of which 45 were excluded. The articles were excluded from the review due to the type of workflow implementation, specific location, and the collection process versus the sample manipulation process. Two additional articles were found using Google Scholar using the similar search criteria for review and six papers in total were reviewed for analysis.

Literature Analysis

Wall and Baldwin (2017) reviewed the standards to implement a workflow for the use of the oncolytic virus (T-VEC), which requires the collaboration of a multidisciplinary team to ensure success. This article addresses the safety implications, preparation, dosing, risk factors, and education for nursing staff. The standards were implemented for 16 patients treated with 77 doses, with no adverse patient or employee events. The team involved with the workflow process for administering T-VEC in an outpatient clinic gave positive feedback. This environment mirrors the assessed microsystem as their setting was also an outpatient oncology setting, for ctDNA kit collection workflow standardization. In addition, the researchers used a multidisciplinary approach that will be useful to this project. Limitations are the number of

facilities in which the T-VEC workflow was implemented, which reduces the transferability to other sites, and the need for outcome data comparable to outcome measures for the ctDNA kit collection implementation.

Lubin et al., (2019), describe multidisciplinary workflow integration for genetic testing in cardiology patients and the risk of inheritable long QT syndrome. By defining treatment and symptom parameters within this workflow, the patients can be identified promptly and placed on lifesaving therapies. This workflow was implemented in the outpatient and emergency room setting to aid in the detection and timely treatment of long QT syndrome in patients. The decision tree steps ensure the process is valuable and potentially lifesaving if followed as indicated. Future indications for this work were addressed related to its transferability based upon varying clinical indicators and testing expansion. The authors address the challenges that providers face in both settings when seeing patients who present with symptoms that may be associated with long QT syndrome. The need to bring expertise to patient care to reduce missed healthcare opportunities by incorporating laboratory and genetic counselors is essential to this work. The limitations include the number or type of tests contractually available to providers in specific settings. Incorporating staff is not a limitation that is relevant to the ctDNA kit collection process because all treatment-based decisions are currently provider based, where long QT syndrome follows published standards of care. This article incorporates the multidisciplinary elements of workflow implementation by way of the diagnostic decision tree to guide providers which is a similar process flow to the ctDNA kit collection. Challenges faced are instrumental in reviewing as they are likely noted in other groups requiring genetic-based testing. The recommendations offer insight to effectivity addressing barriers in other settings.

Tan et al., (2016) used *plan-do-study-act* to implement genetic counselors in the clinic to meet the increasing demand for genetic testing in the cancer care continuum. The methods include the incorporation of process mapping to define the intervention related to patient flow through the clinic to have a consultation with a genetic counselor during a provider visit. Integration of the genetic counselor into the clinic workflow yielded a 2-7 patient capacity increase. The importance of this study is the impact on patient delays and the adjustment of patient flow through a clinic to staff flow and materials in the clinic space. The limitations are the implementation into other clinic spaces and overall delay reduction in time for patients.

Ignatiadis et al., (2021) reviewed the logistical aspects of ctDNA testing regarding the explanation of use, implications for clinical use, and clinic workflow barriers. Incorporation into clinic workflow is a barrier in most settings due to the third-party kit and the multiple vendors that supply them. This review outlines these difficulties noted and touches upon the electronic health record integration. Without the integration there are limitations the usability and efficiency of the results. One limitation was the lack of workflow implementation suggestions related to the process, which will vary in each space used. The relevance is relatable to the proposed future cycles of this quality initiative.

Cutting et al., (2015) discuss workflow implementation relevant to key stakeholders by defining barriers and leveraging solutions to improve the workflow process for in-house genetic testing rather than third-party testing as with ctDNA kits. Similar barriers in implementation were noted in all aspects of the process including, reporting, collection process, and electronic health records integration. Key stakeholders reviewed the workflow and identified potential improvements to the workflow to reduce collection and result reporting errors. Integration into the electronic health record aided in a decrease in patient treatment delays. Limitations for this

article include implementing one health system and that this testing was in-house versus third-party.

White et al. (2021) implemented a metric monitoring plan for turnaround time for the antigen tests HLA-B27 and HLA-B67; these tests are essential for the diagnosis and treatment sensitivities for ankylosing spondylitis. Due to an expected increase in testing demand related to a system merger, the turnaround time for the HLA tests required a monitoring plan. The project reduced turnaround time from 3.8 to 3.3 days using a *plan-do-study-act* model and monitored for three months to ensure sustainability. Limitations of the study noted that the cycles occurred during the COVID pandemic, a time of reduced volume for the testing. The timeframe studied may have impacted the outcome measures of the work. The improvements made during the period of limited volume showed promise, and future cycles could reviewed when the demand for testing increases.

Evidence Synthesis

Each article evaluated offered helpful information to the outpatient clinic process implementation through quality framework definition, process mapping, multidisciplinary team inclusion, implementation tools, data collection, and outcome measure representation. While limitations to each study were present, overall application methods and outcome-driven data helped develop similar workflow implementation projects. Implementing workflows as a quality initiative to improve process flow through outpatient cancer clinics is helpful to reduce total collection time, provide education and improve both staff and patient satisfaction. Projects such as the TVEC workflow implementation are beneficial to ensure regulations for living virus injections to ensure the safety of staff and other patients in the clinic space as described in Wall

et.al (2017). Ignatiadis et al. (2021) detail process initiatives related to education that are useful for workflow implementation within the clinic space with priority related to educational focus in the laboratory. The articles demonstrated the value of workflow implementation and its impact on staff and patients, the literature supports the premise that multidisciplinary approach is necessary, that there are challenges with third party testing and that there is a need for staff education. They assess their contributing role to the workflow during the measure phase of the quality initiative. Cutting et al. (2015) evaluated in-house genetic testing and lab reporting processes related to such, evaluating barriers while developing proposed solutions with key stakeholders for the most effective implementation process. Ignatiadis et al. (2021) review the suggested use, treatment implications, and difficulties that arise while using a third-party testing vendor related to clinic workflow and the education for staff associated with this process. The author needed to detail the steps of process implementation in the review, which limited the reproducibility of the work.

Implications for Quality Initiative

The articles reviewed demonstrated the value of standardized work and the impact the workflow process offers to those who work or are cared for in the cancer center clinic. All researchers discussed essential components influencing the process and development of standardizing ctDNA kit collection, such as a multidisciplinary approach.

Rationale

Implementation using the *plan-do-study-act* framework allows for future cycle testing to evaluate the change and implement adjustments as needed in the ctDNA kit collection process. The *planning* phase analyzes the microsystem through observation, interview, and research. This

phase allowed staff concerns regarding the ctDNA kit collection process to be reviewed and discussed. Decreasing total collection time and improving staff satisfaction directly improve clinic and patient flow through a standardized workflow. Stakeholders would assist in developing the proposed workflow and implementation goals mapped and data collection through chart review to determine the time lapse between order and collection time. The *do* phase will implement the workflow as developed, which includes education related to the workflow and surveying the staff post-intervention. The *study* phase involves data analysis, including time from order placement to completion and staff survey results. During the *act* phase, the dissemination of the work to staff and student colleagues was conducted.

Specific Aims

The aim is to develop a standardized workflow for circulating tumor DNA kit collection to improve the delivery of patient-centered care at the cancer center. Each specialty group within the cancer center utilizes kits from five third-party vendors; the lack of a defined process causes delays impacting patients and staff. The specific aim was to reduce the total collection time from 37 minutes pre-implementation to 15 minutes following the intervention phase concluding on July 28, 2023. Staff satisfaction related to the ctDNA kit collection is low; with the implementation, the goal would be to increase by two points in fifty percent of those surveyed.

Methods

Context

The microsystem mission statement reads, "To prevent and cure cancer through pioneering interdisciplinary research, to translate new knowledge into better prevention and

treatment, and to provide effective and compassionate clinical care that improves the lives of patients with cancer and their families. We are committed to excellence in our research, dynamic partnerships between our laboratories and clinics, robust outreach and education throughout our region, and outstanding education and training programs for future cancer scientists and clinicians". (Dartmouth Cancer Center, 2022, para 2). Embedded within the mission statement is to provide effective and compassionate clinical care through dynamic partnerships. The clinic is home to forty-one providers that serve roughly one hundred and eighty patients per day; the clinic providers utilize multiple shared resources, such as two clinic nurses and four licensed nursing assistants, as well as a lab dedicated to the hematology/oncology population. The space is a square U with clinic rooms making the U shape and the provider workroom and nurse space in the area between. The socioeconomic makeup is diverse, from the employees to the patients serviced. Given the rural location of the facility, many patients require financial support for items ranging from gas cards to the use of the food pantry, medication assistance, and more. The physical space for the proposed intervention needed improvement for the flow of the patients through the space. This was accomplished by improving access to the forms needed to complete the kit collection

Cost Benefit Analysis (CBA)

The time returned to providers through implementing a standard workflow for ctDNA kit collection would be roughly one patient visit per day (sixty minutes) for every three kits ordered. According to Dusetzina et al. (2015), a provider visit fee in an outpatient cancer center clinic is $230, which would return $72,000 per 950 kits in time. Billable lab draws for the kits would charge approximately $100 per kit, resulting in $95,000 in income not previously billed to the third-party vendors.

Intervention

The workflow was developed with nurses, laboratory, and clinic providers and presented through education in provider meetings, nurse meetings, and communication with the laboratory. The workflow process started with the provider determining the need for the ctDNA Kit for oncological treatment and/or disease tracking. The provider then initiates a conversation with the patient regarding the test's purpose and the expected outcomes related to completing the test, then completes and signs the test requisition form with the patient to approve billing through insurance and consenting to get a laboratory blood draw. The next step will be to order the specific kit and a lab draw if no other labs are due to be drawn at that time. The patient will then proceed to the hematology-oncology laboratory for a blood draw. Specimens and labeling are reviewed by phlebotomy and nursing staff to ensure the right patient, kit, and paperwork. The kit is then sent to the company by expedited mailing. The results are returned to the provider for evaluation in email format and then uploaded to the patient's chart (see Figure 2). Implementing this workflow is expected to reduce time waste for patients, providers, nurses, and laboratory staff by having a documented process for each team member to follow. The most significant reductions in wasted time were noted for staff who spent additional time clarifying the process for one another. The workflow process map allows all process members to be knowledgeable and accountable for their role in the kit collection process. Implementing the steps within the workflow will define each step for each team member within the process to allow for the flow of the ctDNA kit to have a person accountable from when the order is received to when sending the specimen. This implementation's success depended on the critical stakeholder support, clear education for staff regarding the process definition, the role each member has, and the direct

impacts it will have on patients. There is no cost to the project as the workflow utilizes staff already involved.

Study of the Intervention

The intervention was studied by chart review to determine the efficiency of the workflow, survey reviews to assess the efficiency concerning the process, and observation to ensure the steps of the process are efficient in the cancer center clinic. To quantify time reduction for ctDNA kit collection a chart review was conducted and total collection time was defined as order placement time to collection time.

Measures

The instrument chosen to study the outcome success of the intervention is chart review, observation, and surveying of critical stakeholders. Chart review measures total collection time, defined as the time of order placed to lab collection time for each patient. Staff time was reviewed by observation to improve flow through the clinic. Surveys were completed one on one with the staff, who were key stakeholders in the development of the process but also the daily work for ctDNA kit collection. Pre- and post-implementation surveys were developed to measure satisfaction; the survey assessed the perception of delays for themselves, patients, and other patients in the clinic. Chart review will consist of patient elapsed time, defined by the time of the order placement to the time of collection. A survey was distributed to determine satisfaction rates with the process before and after implementation. The total collection time was collection through chart review through July 1, 2023 to assess if the outcome measure was met as predicted.

Analysis

The quantitative analysis includes observational and survey data to determine if implementation goals were met. The continuous data collection for total collection time is to be expressed by mean, standard deviations, and range for pre-implementation and one-week post-implementation. Total collection time will compare pre- and post-implementation to assess the outcome measure. Staff satisfaction was collected by survey, and categorical increases were measured by percentage increase or decrease.

Ethical Considerations

There is an important consideration for the protection from the invasion of privacy due to the potential to view other information when collecting time data of order and collection timestamps. This proposal was submitted to the University of New Hampshire, the Department of Nursing Quality Review Committee, and the Nursing Leadership for the Cancer Center for internal review. This project was determined to be a quality initiative exempt from full Institutional Review Board review.

Results

Results

Within the cancer center, ctDNA kits are used to monitor residual disease, identify genetic mutations and identify undetected circulating diseases. Providers within the clinic space use the technology driven results that the results that the kits offer and five different kits are utilized in the cancer center to help guide treatment decisions. During the assessment of the clinic, it was identified that there was no defined process for collecting ctDNA kits. The absence

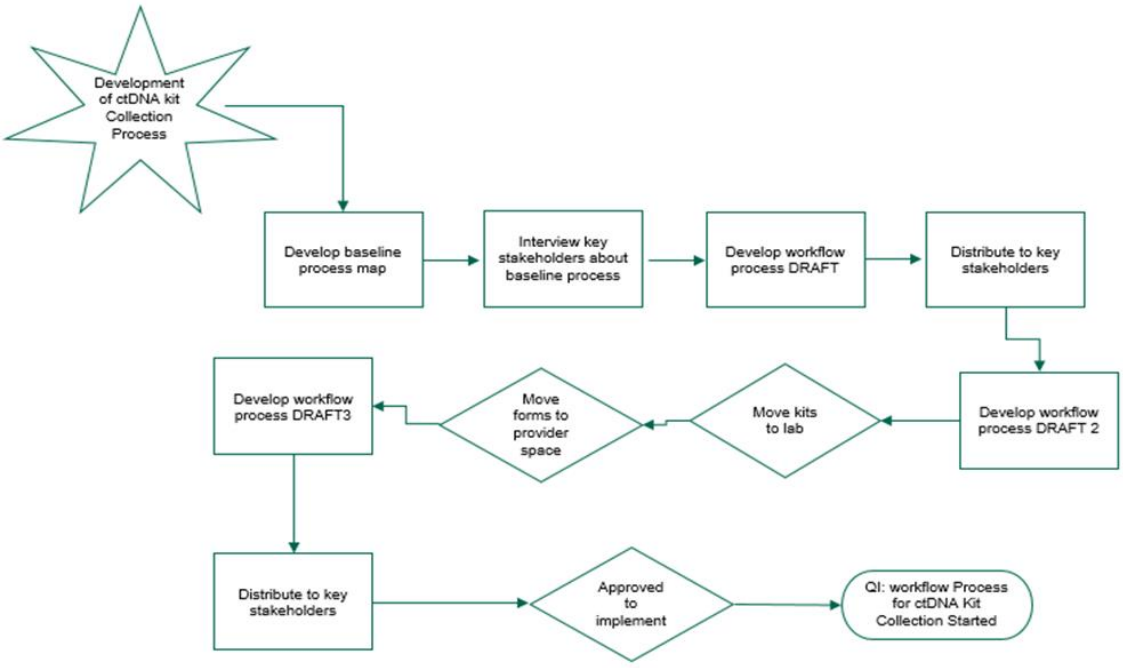
of a process negatively impacts staff and patients. Over the last few years, the increased use of ctDNA kits has highlighted the need to develop a standardized workflow to reduce total collection time, positively impacting all.

Initial Steps of the Intervention

The initial steps of the intervention began in spring 2023 with the microsystem assessment, which led to the review of the ctDNA kit collection process. Baseline process mapping was utilized to determine the causes for delays or significant lapses in time related to ctDNA kit collection. Interviewing staff to understand the barriers in the pre-implementation process was necessary for standardization workflow development. A draft of the ctDNA kit collection workflow was shared with key stakeholders for feedback; once all groups shared feedback, modifications were made to the workflow and the workspace to meet all stakeholder's needs in the process (see Figure 1.). Process improvements included file holders being mounted in the provider workrooms to house the test requisition forms, and cabinet space was provided in the cancer center lab to store the kits and allow for direct stocking.

Figure 1.

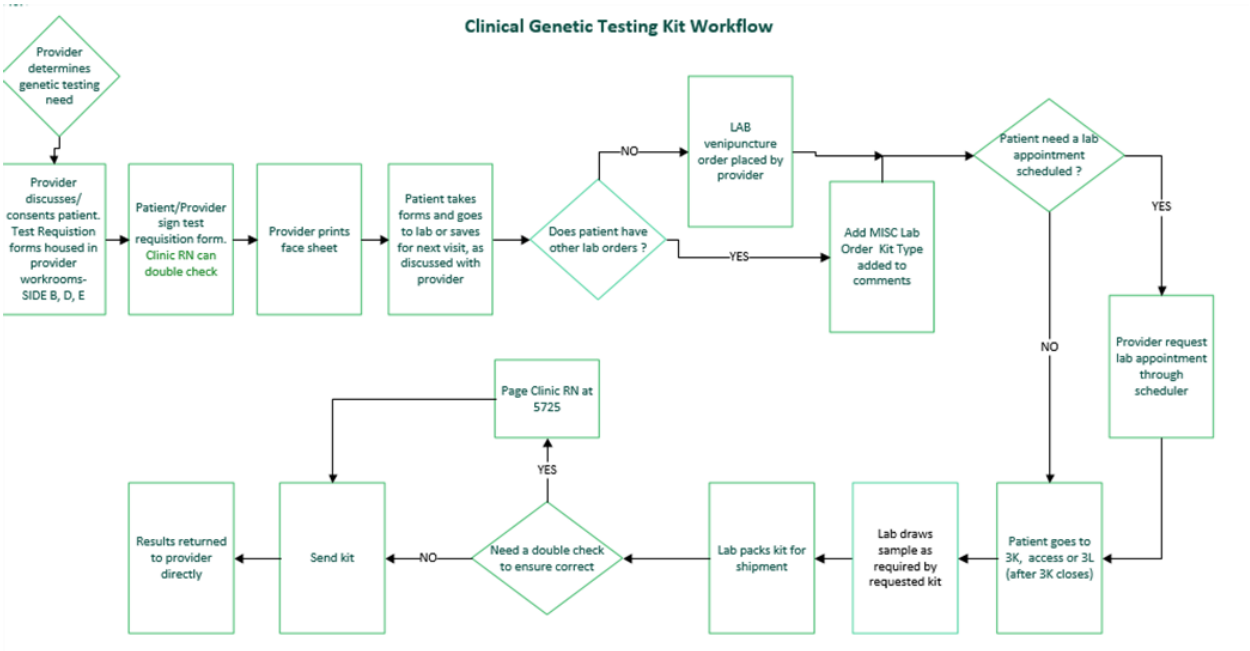
Workflow Development Process Map



Starting June 2023, education for the workflow process was provided to all staff involved before the June 26, 2023 implementation. Education for the providers included test requisition form requirements for each kit, reinforcing the scope of the other team members in the process and the inability of phlebotomists or nurses to obtain signatures. The location of the forms in the provider workspace included details of who to contact for supply needs and who to contact for ctDNA kit collection assistance. Clinic and triage nurses received education about the expectations of all team members with guidelines for how they could assist with a double check in the lab setting and the resource role for providers. Laboratory staff were educated about the expectations of other team members, as well as collection requirements and mailer details. Key responsibilities were outlined to each group separately in small group meetings and through *Situation-Background-Assessment- Recommendation* (SBAR) communication via email. The workflow process and SBAR regarding the ctDNA kit collection workflow were delivered at staff and faculty meetings.

Figure 2.

Standard Workflow for Implementation



Surveys were developed to assess staff satisfaction before implementing the standardized workflow and post-intervention. The survey could be repeated following subsequent cycles as the process evolves and given team feedback. Both faculty and practice mentors reviewed the survey questions to assess the questions to ensure they adequately captured process satisfaction.

Total Process Collection Time

The measure for total process collection time for ctDNA kits was captured by chart review of order details for the time of order entry to time specimen was collected, by the laboratory timestamps. The data omitted from the analysis were orders entered for a future date or subsequent visit. The implementation process success was measured by decreasing the average time from order placement to order collection. Pre-implementation data was collected

during the planning phase of April 2023. The total process collection time before workflow implementation was noted as a mean of 37 (SD 6.91, Range of 16-48). Following the implementation, the mean was noted at 19(SD 3.94, Range 13-20).

Table 1.

Total Process Collection Time

Time Waste in Minutes n=10 Charts Reviewed	**Pre-Implementation**	**Post-Implementation**
Mean	37	19
Standard Deviation	6.913	3.974
Range	16-48	13-20

Staff Satisfaction Survey

The survey analysis addresses the score on the pre- and post-implementation workflow for ctDNA kits using a 3-point Likert scale, with 1 indicating not satisfied, 2 indicting neutral perception and 3 indicting satisfaction. Prior to implementation, staff reported low satisfaction on a scale of 0-3 and averaged 1.1 with an n= 6. Additional comments on the surveys addressed the need for a defined process and education related to the purpose of the tests to the staff involved. Following implementation of the revised workflow staff satisfaction increased, see Table 2.

Table 2.

Staff Satisfaction Survey Data

Staff Satisfaction Likert Scale Survey 1-3	Pre-Implementation n=6 Frequency	Percentage of Frequency	Post-Implementation n=7 Frequency	Percentage of Frequency
Score of 1	5	83%		0%
Score of 2	1	17%	2	29%
Score of 3		0%	5	71%
Mean	1.167		2.714	
Standard Deviation	0.373		0.471	
Range	1		1	

Observations

Identifying providers that are the highest users was crucial when developing and adhering to the proposed workflow. Creating space in provider workrooms where the required paperwork was housed with mandatory tasks for the provider to complete posted for the kit process was suggested by those stakeholders; this was useful in directing providers who use these tests less frequently. Storing the kits in the lab space returned time to providers by eliminating the need to walk through the clinic where they were previously held. Outlining the provider's and clinic staff's requirements, the laboratory reduced the communications sent regarding these tests. Unexpected benefits were that laboratory leadership needed to be made aware these were not research-based kits, and billing back to the companies for the lab draw was not occurring. Therefore, the health system was absorbing the cost. Once aware, contractual agreements were established to allow for reimbursement for phlebotomy services. Many ctDNA kit companies allow integration into the electronic medical record system. At the same time, this portion was not approved for this cycle of workflow process implementation, and it is the next step for the system. Integration would substantially benefit the provider group in how they receive patient results.

Discussion

Summary

The purpose of this quality initiative was to develop a standard workflow for the collection of ctDNA kits within the cancer center. The specific aim of this project was to reduce the total collection time from 37 minutes to 15 minutes following the implementation of a standardized workflow. While the specific aim was not met, the total collection time was reduced to a mean of 19 minutes per patient. A second specific aim was to increase staff satisfaction by 50% which was achieved. Using a *plan-do-study-act* model allows for future cycles to be run, allowing for continued optimization of the workflow. There were several key findings, including substantial knowledge deficits, improvement in total collection time and increased staff satisfaction.

Key Findings: Knowledge Gaps

The *planning* phase of the quality initiative outlined the need for knowledge within the clinic space regarding the ctDNA test kit. The most striking knowledge deficits were the tests' purpose and relevance to treatment-based decision-making and that the test is not related to an active research study. These knowledge deficits were identified in the laboratory and nursing staff. A part of the initial implementation included education to these staff members related to the intent of the ctDNA test kits, as well as the changes that occurred within the laboratory space. The laboratory leadership was unaware of the purpose or origins of the test kits. Once education was provided, it was discovered that the ctDNA kits were not under contract with our facility. Due to this lapse the phlebotomy draws were absorbed and as a result of the quality initiative will now be billed to the kit companies the health system absorbs research-based blood draws, which were falsely identified as research kits. In addition, circulating tumor DNA kits can now

be handled through the health system mail service, which reduces the number of steps for the clinic staff and allows for tracking of the kit throughout the facility and mail service, leading to better accountability.

Key Findings: Opportunities for EMR Integration

It was discovered that most of the kits could be integrated into the EMR for more seamless ordering and result return; At the same time, the scope of the workflow implementation could not accommodate that work; the informatics team graciously met with the project lead and kit company representatives to discuss this work and place it on a queue of future projects.

Key Findings: Improvement in Total Collection Time and Staff Satisfaction

While staff satisfaction with the kit collection process was low before implementation, there was significant support to ensure a robust, standardized process was developed within the current quality initiative and potential future cycles. Total collection time was 37 minutes prior to implementation and improved to 19 minutes following implementation. Improvements in both staff satisfaction and total collection time reduction resulted in positive outcomes for the patients.

Project Strengths

The strengths of this quality initiative are the standardization of work to improve patient and employee satisfaction. Within this project, the knowledge gained by staff regarding the purpose of the tests, total collection time reduction, and unexpected financial gain due to the returned time are all outcomes that enhance the patient experience and staff satisfaction. There was a high level of stakeholder support which aligned with the literature reviews noting the importance for implementation success.

Interpretation

Intervention versus Outcome

Following the workflow implementation, key stakeholders were likelier to complete the tasks within their scope. The test requisition forms were completed fully for each patient during the one-week observation period, allowing the laboratory team to process the collection step with minimal delays. The process steps were followed as part of the intervention, and the outcome would be measured as successful based on the total collection time and satisfaction data. The workflow process implementation allowed each key stakeholder to understand their role within the process to ensure completion. The education provided to each group focused on each stakeholder's role and how each step is required in the process as outlined to reduce not only time waste but reduce patient safety risks such as lab collection and labeling errors, packaging errors, form errors, and inadequate patient knowledge related to the purpose of the testing.

Impact of the Project on People and Systems

During the key stakeholder review of the process, there was a concern for resistance related to the form completion steps and the requirement for completion before the patient goes to the lab due to the potential for the patient to go to the lab twice in one day. To reduce the risk of improper labeling and consenting based on the companies' requirements, the form must be completed before the patient presents to the lab. Education was provided with the intent of this step being first in the workflow; there was a considerable change in the annoyance related to that step. Potential barriers outlined to the clinic-based process were assessed, such as the collection of clinic patient samples where they are admitted to the inpatient setting and the process for other departments within the hospital using these tests for disease monitoring. The identified barriers

could be addressed in future cycles of the implementation process to ensure all departments within the system using this testing kit would follow a similar process.

Through the workflow development, it was identified by laboratory leaders that the kit companies used did not have a contract with the Health System. Due to this, the laboratory order providers use a research phlebotomy draw. The blood draw order is not billed to the patient but absorbed by the healthcare system. By identifying this gap, contract specialists were consulted, and contracts were developed for the companies. This will ensure billing for the draw and revenue that did not exist related to the collection process. This is outside of the scope of this quality improvement; however, the implications are positive from a revenue standpoint.

Observed and Anticipated Outcomes

While most outcomes were as anticipated, many opportunities were identified for future cycles that would benefit the Cancer Center Clinic such as billing related to laboratory blood draws and ctDNA kits. In addition, electronic health record integration could provider results directly to providers. These are outside of the scope of this initiative but would be helpful to explore for future cycles related to this project. Most literature reviews with comparative projects indicated a successful implementation. This is especially true for those that were created when a process was utterly lacking. By utilizing key stakeholders and assessing patient delays, it was expected that both would be effective as it improves clinic workflow for patients and staff. The education piece was not anticipated during the *assessment* phase. This aligned with a similar implementation in Cutting et al. (2015) for all parties involved. It was assumed that all clinic staff members knew the purpose of the test and this additional education added time to the process development.

Cost-Saving Opportunities Identified

Cost savings related to this initiative would include reducing time waste, which would be acknowledged in workable time returned to the cancer center clinic staff. Reducing patient delays will improve patient satisfaction and reduce labeling errors related to incomplete forms or improper tube labeling. This can cause the kits to be rejected and would require a re-draw.

Limitations

An initial limitation identified within the project was the lack of similar workflow process improvements specific to the ctDNA kit collection process; the literature review focused narrowly on workflow for kit collection. Expansion to other workflows in similar settings with similar teams was necessary to review for guidance. This hindered the identification of measures for the project's success and potential barrier identification due to the specificity. The second limitation was a company changing the test requisition form just days before the implementation, initially set for June 26, 2023. This delayed the intervention implementation, which reduced observation time to determine barriers that may still be impacting the process and suggested development for future cycles. The third limitation was the number of provider staff to return feedback on the process, while most were engaged. Some key stakeholders were not involved in the process development due to clinical time obligations; their feedback was noted through other providers involved in the process development to mitigate this, which may negatively impact compliance with the process. The last identified limitation was that new staff in the clinic needed to be made aware of the clinical indications for ctDNA kits. This led to additional education about the test purpose and workflow implementation. This also impacted the project due to the decreased knowledge of the clinic flow for patients and staff.

Previous clinic workflow projects were reviewed to ensure key stakeholder support, especially from a leadership standpoint. Observations were made, and key stakeholders were consulted to ensure support in the process and to translate the importance to newer staff. The potential impact of the company changing the form delayed implementation for the ctDNA kit collection workflow to ensure all changes were made at once instead of a kit-specific timeline. This aided in communications reductions and confusion related to the implementation timeline.

Conclusion

Workflow implementation improved the clinic flow by reducing patient in-room time that previously would have delayed other patient visits. This addresses the workflow implementation success at reducing staff time at completing the tasks related to the ctDNA collection process. While this workflow will likely be modified in future cycles due to the potential progress in developing contracts, and electronic health record integration, the current improvements were noted to be significant by users. The use of ctDNA kits is only increasing in the Cancer Center Clinic and other clinic spaces within the health system. Therefore, this workflow could be implemented in other settings with modifications. The Cancer Center clinic has a designated lab space allowing flexibility in developing this workflow due to the existing proximity and patient population knowledge. Suggested next steps for future cycles for the workflow would be contract development with the vendors to ensure proper billing for the lab draws, which would increase laboratory revenue each year. With the contracts, the kits could be part of the health system mailer program, which allows for increased tracking and more efficiency when mailing the kits. Integrating the electronic health record would ease result reporting frustrations for the providers and give access to other healthcare providers that may care for the patient. A workflow inefficiency resulted in patient delays and staff frustration.

This project aimed to reduce total collection time and improve satisfaction related to the ctDNA kit collection process. Following implementation, time was reduced, and staff satisfaction improved. Future cycles would continue to improve the current specific aims of the initiative and could expect to improve patient-centered care within the clinic.

References

Cutting, E. M., Overby, C. L., Banchero, M., Pollin, T., Kelemen, M., Shuldiner, A. R., & Beitelshees, A. L. (2015). Using Workflow Modeling to Identify Areas to Improve Genetic Test Processes in the University of Maryland Translational Pharmacogenomics Project. AMIA ... Annual Symposium proceedings. AMIA Symposium, 2015, 466–474.

Dartmouth Cancer Center. (2022). Dartmouth Cancer Center Mission & Vision. Retrieved February 14, 2023, https://cancer.dartmouth.edu/about/mission-vision

Dusetzina, S. B., Basch, E., & Keating, N. L. (2015). For uninsured cancer patients, outpatient charges can be costly, putting treatments out of reach. Health Affairs (Project Hope), 34(4), 584–591. https://doi.org/10.1377/hlthaff.2014.0801

IEHSS. (2022). Knowledge Center. Retrieved February 1, 2023. https://clinicalmicrosystem.org/knowledge-center/worksheets/

Ignatiadis, M., Sledge, G. W., & Jeffrey, S. S. (2021). Liquid biopsy enters the clinic - implementation issues and future challenges. Nature reviews. Clinical oncology, 18(5), 297–312. https://doi.org/10.1038/s41571-020-00457-x

Lubin, I. M., Lockhart, E. R., Frank, J., See, V. Y., Vashist, S., & Greene, C. (2019). Challenges and opportunities for integrating genetic testing into a diagnostic workflow: heritable long QT syndrome as a model. Diagnosis (Berlin, Germany), 8(1), 17–26. https://doi-org.unh.idm.oclc.org/10.1515/dx-2019-0018

Ogrinc, G., Davies, L., Goodman, D., Batalden, P., Davidoff, F., & Stevens, D. (2016). SQUIRE 2.0 (Standards for Quality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. BMJ quality & safety, 25(12), 986–992. https://doi.org/10.1136/bmjqs-2015-004411

Tan, R. Y., Met-Domestici, M., Zhou, K., Guzman, A. B., Lim, S. T., Soo, K. C., & Ngeow, J. (2016). Using quality improvement methods and time-driven activity-based costing to improve value-based cancer care delivery at a cancer genetics clinic. Journal of oncology practice, 12(3), e320-e331

Wall, L. M., & Baldwin-Medsker, A. (2017). Safe and Effective Standards of Care: Supporting T-VEC administration for patients with advanced melanoma in the outpatient oncology setting. Clinical Journal of Oncology Nursing, 21(5), E260–E266. https://doi-org.dartmouth.idm.oclc.org/10.1188/17.CJON.E260-E266

White, E., Proudlove, N., & Kallon, D. (2021). Improving turnaround times for HLA-B*27 and HLA-B*57:01 gene testing: a Barts Health NHS Trust quality improvement project. BMJ open quality, 10(3), e001538. https://doi.org/10.1136/bmjoq-2021-001538