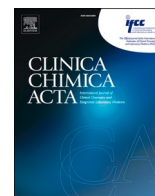




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The impact of biosafety enhancement on stat laboratory quality metrics: Lessons from the COVID-19 pandemic

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ABSTRACT

Objective: It is unclear if implementation of biosafety action plans in response to the COVID-19 pandemic has affected laboratory quality metrics.

Methods: This retrospective study used quality data, including turnaround time (TAT) and number/type of unacceptable specimens from a stat laboratory supporting an outpatient medical clinic serving predominantly elderly cancer patients. Four months of data from the height of the COVID-19 pandemic (March–June 2020) were compared to the same months in 2019.

Results: March–May 2020 test volumes were decreased compared to 2019. June 2020 test volume was slightly increased compared to 2019. TATs in 2020 were similar/ slightly improved compared to the same months in 2019, due to shortened collect to receive and receive to verify TATs. The number and types of unacceptable specimens were similar in 2020 and 2019.

Conclusions: Despite the challenges to the system caused by the pandemic, laboratory quality metrics were maintained.

1. Introduction:

The COVID-19 pandemic, which originated in Wuhan, the capitol of the Hubei Province of China, has had a worldwide impact on many facets of human activity. In the absence of a vaccine or widespread natural immunity, most nations have adapted the tenets of social distancing, wearing of masks when in public, and limited work hours, all in an effort to limit exposure and spread of the SARS-CoV-2 virus. These policies have extended to the clinical laboratory: a recent survey reported that laboratories have decreased the items available in their test menus, staggered staffing to limit individual employee exposures, implemented employee temperature checks, and increased the decontamination of the workplace and clinical instruments [1]. The impact of these changes on laboratory turnaround time (TAT) and other quality metrics has been largely unexplored [2]. The impact of the COVID-19 pandemic on overall test volume has also largely been unexamined.

Since stat laboratories often serve a high fraction of patients with comorbidities such as age > 60 years and cancer, which have been associated with severe disease and poor prognosis in SARS-CoV-2 infection [3–6], it is essential for these laboratories to support their clinical

services in a way to minimize patient wait times and still maintain acceptable quality. The purpose of this study was to examine the outcomes, as measured by quality metrics, of the policies implemented by a stat laboratory operating in a hematology/oncology outpatient clinic, in response to the COVID-19 pandemic.

2. Patients and Methods:

This study was performed at an outpatient facility staffed by university faculty physicians. The patient population consists almost entirely of patients with established or suspected history of hematologic malignancy or solid tumor, and ~ 85% of patients are > 60 years of age.

The College of American Pathologists/ Clinical Laboratory Improvement Act-certified laboratory is staffed by 2 medical technologists and 2 phlebotomists. The test menu consists of complete blood count (CBC) with or without differential count, basic chemistry panels, lactate dehydrogenase, magnesium, uric acid, amylase, and lipase. Instrumentation consists of a Sysmex (Kobe, Japan) XN-10 blood analyzer and a Roche (Basel, Switzerland) C501 chemistry analyzer.

The first case of SARS-CoV-2 infection was reported in the region on

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March 8, 2020 and the increased number of reported infections in the area resulted in the following changes to the standard operating procedures of the outpatient clinic and laboratory, which were implemented starting the week of March 19. Access to the facility was limited to employees, patients, and no >1 additional individual accompanying a patient. All persons entering the facility were temperature-checked upon arrival and were screened for risk factors before being allowed entry. Social distancing was implemented in the waiting area by placing seats ~ 6 feet apart.

A high fraction of patients are being actively treated with adjuvant chemotherapy and other treatment protocols for which rapid turnaround time is necessary, and patients frequently are required to wait in the clinic for the results of laboratory tests before being allowed to leave. For this reason it was decided that 1) the laboratory menu would be unchanged, rather than shift any of the testing to the main laboratory, 17 miles (~27 km) from the outpatient facility 2) the level of staffing

would be minimally reduced by 10% to decrease the risk of transmission between employees and maintain (or improve) TAT 3) batching of specimens by the phlebotomy staff before transport to the laboratory would be minimized to decrease collect to receive TAT 4) laboratory procedures should be carefully reviewed by lab personnel to ensure that all testing was performed efficiently and correctly, to ensure that intralaboratory TAT was maintained 5) special attention would be given to efforts to minimize exposure of employees (e.g. masking of employees at all times, frequent hand washing, frequent decontamination of instrument and counter surfaces).

This study protocol was reviewed by the University Human Research Protection Office which determined that it did not involve activities that are subject to Institutional Review Board oversight.

Data entry and graphical presentation was performed using Excel (Microsoft, Redmond, CA USA) and statistics were performed using Minitab 18.1 (State College, PA USA). The following statistics were

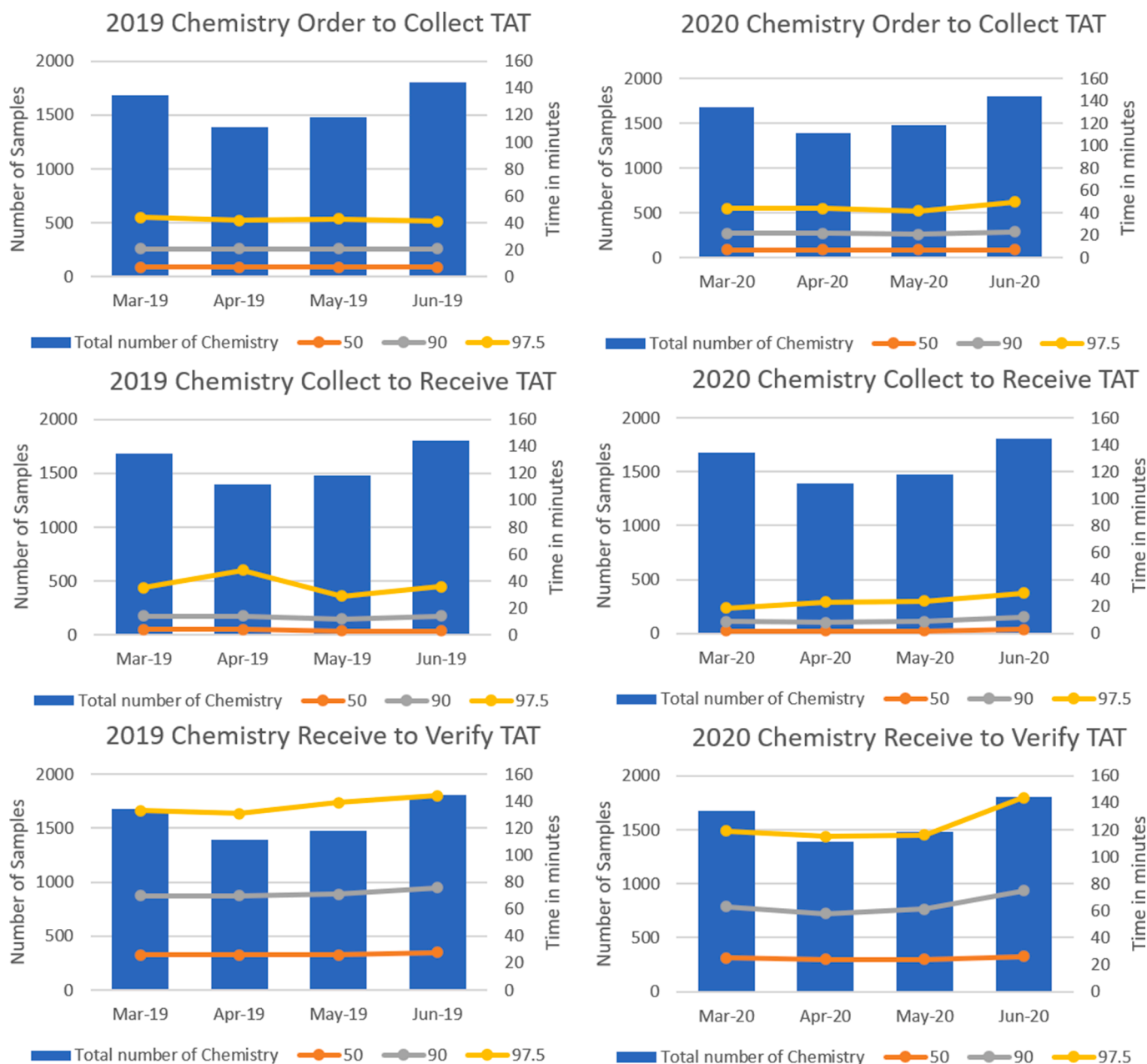


Fig. 1. Chemistry order to collect, collect to receive, and receive to verify turnaround times (TATs), showing 50th, 90th, and 97.5th percentile TATs superimposed on monthly testing volume for March-June 2019 (left side) and March-June 2020 (right side).

recorded or calculated: number and type of unacceptable specimens (clotted specimen, collection error, hemolyzed specimen, intravenous contamination, laboratory accident, laboratory order error, mislabeled specimen, quantity not sufficient, expired specimen); mean monthly test volume; and TATs, separated into order to collect TAT, collect to receive TAT, and receive to verify TAT. The study period was March- June 2020, which included the first month the protocol changes were implemented and the last full month for which data was available. The statistics for the study period were compared to the same months in 2019. Since TAT statistics had a nonnormal distribution, comparison was performed using Mann-Whitney U-statistics, which also took into account the differences in testing volume between 2019 and 2020. A p value of < 0.05 was considered statistically significant.

3. Results:

Graphs of order to collect, collect to receive, and receive to verify TATs superimposed on monthly testing volume for 2019 and 2020 are illustrated in Fig. 1 (chemistry) and Fig. 2 (hematology). The overall test

volume in March 2020 was slightly lower than the comparable period in 2019 (3425 vs 3495, -2%) and dropped sharply in April 2020 (2889 vs 3714, -22%) (Table 1). The testing volume in May 2020 remained depressed (3086 vs 3317, -7%) and increased in June 2020 to surpass the test volume of June 2019 (3744 vs 3655, +2%).

Table 1 shows the results of Mann-Whitney U-statistics comparing the median order to collect, collect to receive, and receive to verify turnaround times for each month during the study period to their comparable month in 2019. Order to collect turnaround times remained stable throughout the study period. There was a significant improvement in the chemistry collect to receive turnaround times for all months and for March and April for the hematology testing, as evidenced by the marginally decreased median and interquartile ranges for these periods. There was a slightly improved chemistry receive to verify turnaround time for March-May 2020 compared to 2019. The hematology receive to verify turnaround times were relatively constant over the study period and did not significantly differ from those in 2019. Looking at the graphical description of the collect to receive turnaround times (Fig. 1), it is seen that the improvement in turnaround times was due to

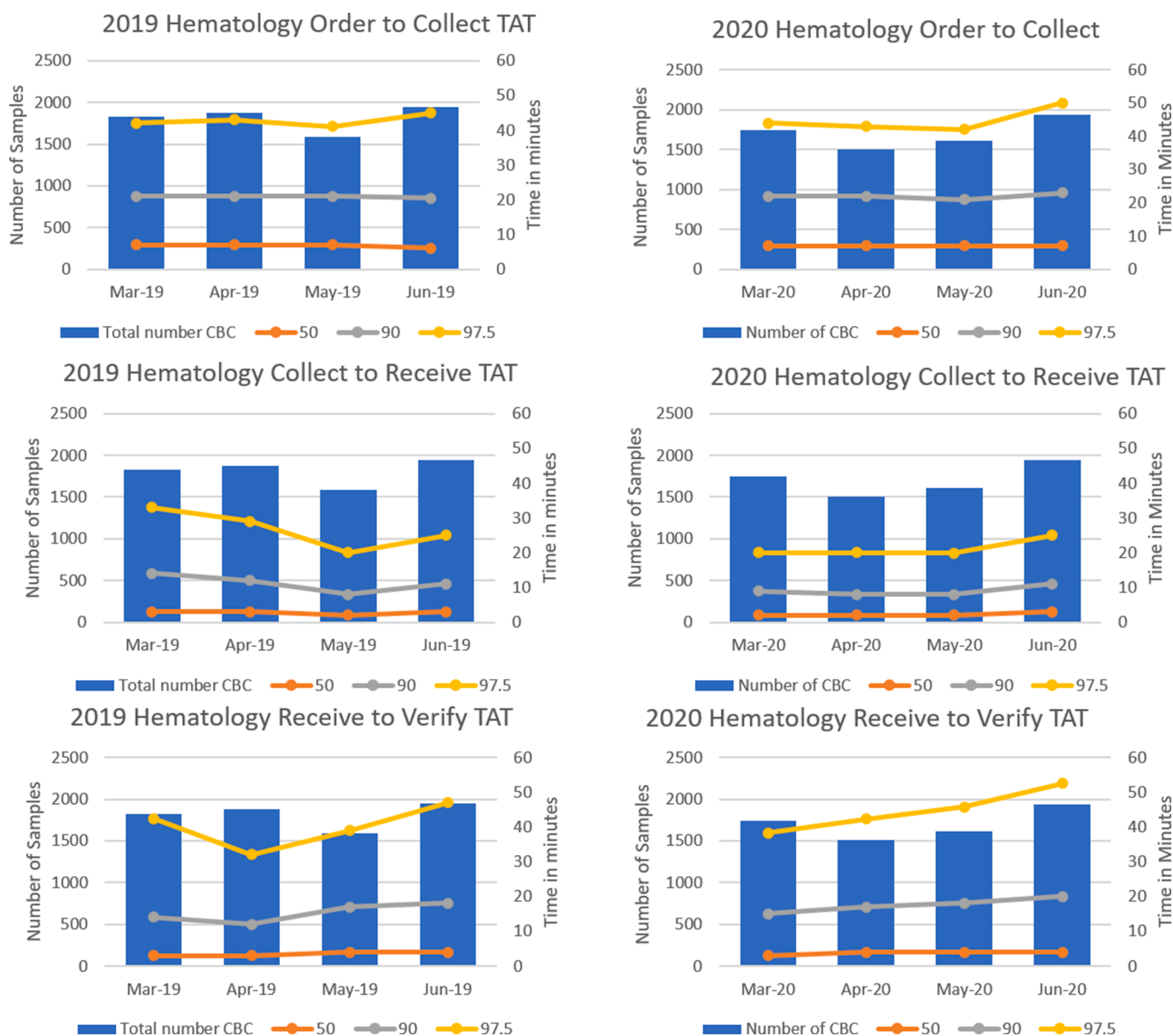


Fig. 2. Hematology order to collect, collect to receive, and receive to verify turnaround times (TATs), showing 50th, 90th, and 97.5th percentile TATs superimposed on monthly testing volume for March-June 2019 (left side) and March-June 2020 (right side).

Table 1
Comparison of order to collect/collect to receive/receive to verify turnaround times March-June 2019 vs March-June 2020.

		March			April			May			June		
		2019	2020	p	2019	2020	p	2019	2020	p	2019	2020	p
	Total testing volume (n)	3495	3425		3714	2899		3317	3086		3655	3744	
Chemistry	Number of Specimens (n)	1667	1679		1840	1392		1729	1477		1710	1806	
Turnaround times, median and (IQR), mins	Order to collect	7 (5–10)	7 (5–10)	0.997	7 (5–10)	7 (5–10)	1.000	7 (4–10)	7 (5–10)	1.000	7 (4–10)	7 (5–11)	1.000
	Collect to receive	3 (3–6)	2 (1–4)	<0.001	3 (2–6)	2 (1–4)	<0.001	4 (2–6)	2 (1–4)	<0.001	4 (2–7)	3 (1–5)	<0.001
	Receive to verify	28 (23–35)	25 (22–31)	<0.001	26 (22–33)	24 (22–28)	<0.001	25 (22–31)	24 (21.5–29)	<0.001	26 (22–33)	26 (23–34)	0.989
Hematology	Number of Specimens (n)	1828	1746		1874	1507		1588	1609		1945	1938	
Turnaround times (median and (IQR), mins)	Order to collect	7 (5–10)	7 (5–10)	1.000	7 (4–10)	7 (5–10)	1.000	7 (4–10)	7 (5–10)	1.000	6 (2–10)	7 (5–11)	1.000
	Collect to receive	3 (2–6)	2 (1–4)	<0.001	3 (2–6)	2 (1–4)	<0.001	2 (1–4)	2 (1–4)	0.236	3 (1–5)	3 (1–5)	0.477
	Receive to verify	3 (3–6)	3 (3–6)	0.787	3 (3–5)	4 (3–7)	1.000	4 (3–8)	4 (3–8)	0.960	4 (3–8)	4 (3–9)	0.876

IQR = interquartile range

the decrease in the outliers, as evidenced by the decrease in the 97.5th percentile line. For chemistry, the collect to receive turnaround time persisted even after the test volume increased in June 2020 to surpass the June 2019 vol For the other TAT metrics, the June 2020 values were not significantly different from June 2019.

The number and types of unacceptable specimens received by the laboratory are listed in Table 2, which compares the 2019 and 2020 data. The number of unacceptable specimens remained constant over the study period and were identical to those recorded for 2019. In 2019 these errors accounted for 0.22% of the testing volume. In 2020 these errors accounted for 0.24% of the testing volume.

4. Discussion:

We report the results of a retrospective study examining successful implementation of an action plan by the stat laboratory of an outpatient hematology/ oncology clinic in response to the COVID-19 pandemic. When we adapted this strategy, there were few reports to assist the planning for a laboratory response to the COVID-19 pandemic. Initially, most publications in the medical literature regarding COVID-19 and laboratory planning were largely speculative in nature and limited to review articles and editorials [2]. Other papers were more applicable to direct patient care rather than being laboratory-specific or were related to treatment and testing of infected patients or individuals with suspected infection. Barba et al, for example, describing the response in an academic center in Madrid, stated that the care of non-COVID patients was reduced [7]. Likewise, DeJonge et al, referencing guidelines proposed by Willan et al [8–10] suggested that clinicians make appropriate decisions regarding testing indication and frequency before sending a patient for phlebotomy. Other guidelines proposed by DeJonge et al and others [11] included segregation of COVID-positive from COVID-negative patients, minimal use of paper forms, social distancing, appropriate use of personal protective equipment by laboratory personnel, and frequent hand washing and other hygienic procedures to minimize spread [8].

Recently, reports have appeared in the literature that describe a variety of responses to the pandemic. Lopic et al reported their experience in a university hospital setting, where it was decided during the pandemic to divert the entire testing volume of an emergency

Table 2
Number and types of unacceptable specimens during the study periods.

Error type	March-June 2019	March-June 2020
Clotted specimen	3	5
Collection error	3	3
Hemolyzed specimen	10	12
IV contamination	1	0
Laboratory accident	4	1
Laboratory order error	3	8
Quantity not sufficient	6	2
Specimen expired	2	1
Total	32	32

department-based satellite laboratory to the hospital’s central laboratory [12]. They reported a statistically significant prolongation in TAT due to increased time from specimen collection to specimen receiving [12]. This strategy would likewise have been unsuccessful in our laboratory, due to the long distance (17 miles) and transit time for specimens to be transported from the outpatient clinic to the main hospital laboratory. Also, based on our experience we were successful in modestly decreasing the collect to receive portion of the TAT, but were not able to decrease the order to collect or receive to verify TATs.

A survey of > 1000 hospital laboratories by The International Federation of Clinical Chemistry and Laboratory Medicine Taskforce on COVID-19 included data from 69 (5.7% of total) outpatient laboratories [1]. Overall, the laboratories participating in the survey cited shortages of personal protective equipment, reagents, and analytical equipment as the most serious material issues. Interestingly, only about one third of laboratories reported daily temperature testing of staff and ~ 50% of laboratories staggered their employee schedules to lower risk of contact with infected employees [1]. In our laboratory, daily temperature checks of employees and all others entering the outpatient facility have been routinely employed, although a recent review suggests that ~ 45% of individuals with COVID-19 are asymptomatic and may not be febrile [13]. Although the baseline number of employees in this laboratory was low, we decided to stagger employee hours, as was done by our hospital’s main laboratory and which has been recommended in a recent simulation study [14].

At our medical center a decision was made to limit the number of

patient visits during the first weeks of the pandemic. This resulted in a marked decrease in clinical volume in the stat laboratory from the last 2 weeks in March through the month of April, with a subsequent increase in volume beginning in May. This phenomenon has been reported by others [15].

We also compared the numbers and types of preanalytical errors from the peak months of the pandemic to those reported in the same months in 2019. The error rate was similar for both periods, with errors accounting for 0.22% of specimens in March–June 2019 compared to 0.24% for the comparable period in 2020. A specific pattern of error was not identified. Although it is difficult to draw conclusions about the effects of biosafety enhancements on preanalytical errors due to the low frequency of these errors, these data suggest that preanalytical errors were not markedly different in 2020 compared to 2019. The distribution of preanalytical errors differs from that described by Narula et al, in their survey of preanalytical errors in a tertiary care medical center laboratory, in which inadequate sample-to-anticoagulant ratio, insufficient sample for analysis, and incomplete requisitions were the main error types [16]. The overall error rate was within the range of previously reported studies [16–20].

There were a few limitations to this study. These included the retrospective study design and the fact that data were derived from a single institution. Although the data were derived from a patient population consisting of largely elderly individuals with cancer, we believe that this information may be generalizable to other populations.

5. Conclusion:

The purpose of this study was to explore a knowledge gap in the existing medical literature regarding the degree to which changes in the operation of a clinic and laboratory to minimize patient and employee exposure to COVID-19 impact laboratory quality metrics. Our findings support our hypothesis that the implementation of these changes would not significantly impact laboratory quality as measured using these metrics despite an overall increase in laboratory volume in the last month of the study period. We conclude that this plan can be successfully re-introduced in the event of a second wave of SARS-CoV-2 infections or similar infectious disease outbreak, and that our plan may be generalizable for use in stat laboratories that serve a population with a high fraction of at-risk co-morbidities.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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