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The effect of the Covid-19 shutdown on glycemic testing and control

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ABSTRACT

Background: The coronavirus disease 2019 (COVID-19) pandemic caused a halt to in-person ambulatory care. We evaluated how the reduction in access to care affected HbA1c testing and patient HbA1c levels.
Methods: HbA1c data from 11 institutions were extracted to compare testing volume and the percentage of abnormal results between a pre-pandemic period (January-June 2019, period 1) and a portion of the COVID-19 pandemic period (Jan-June 2020, period 2). HbA1c results greater than 6.4% were categorized as abnormal.
Results: HbA1C testing volumes decreased in March, April and May by 23, 61 and 40% relative to the corresponding months in 2019. The percentage of abnormal results increased in April, May and June (25, 23, 9%). On average, we found that the frequency of abnormal results increased by 0.31% for every 1% decrease in testing volume ($p < 0.0005$).
Conclusion: HbA1c testing volume for outpatients decreased by up to 70% during the early months of the pandemic. The decrease in testing was associated with an increase in abnormal HbA1c results.

1. Introduction

The year 2020 brought with it the coronavirus disease 2019 (COVID-19) pandemic that resulted in a global shutdown [1]. In March 2020, after the World Health Organization (WHO) declared the pandemic, many outpatient clinics were closed to in-person visits in an attempt to slow the spread of disease. This resulted in many institutions scrambling to get telehealth platforms in place to provide continuity of care to their patients with chronic diseases. In Northern America (U.S. and Canada), diabetes mellitus is amongst the most prevalent chronic diseases [2,3]. Primary care teams screen and make the initial diagnosis of diabetes mellitus. Standard of care for people with diabetes mellitus includes follow up visits every 3–6 months depending on the patient's medication regimen and the previous glycemic control [4]. In both scenarios, measurement of HbA1c typically occurs at the time of these in person visits and is essential for monitoring glycemic control.

With the shift to telehealth, many diabetes centers had to adjust their chronic care flow. In Padua, Italy, there was a 47.7% decrease in outpatient diabetes visits during shutdown [5]. With this reduction, they saw that older patients with more comorbidities were less likely to be

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seen. Worryingly, the use of medications to reduce complications from diabetes mellitus was decreased.

2. Methods

HbA1c data from 11 institutions was extracted to compare testing volume and the percentage of abnormal results between a pre-pandemic period (January-June 2019, period 1) and a portion of the COVID-19 pandemic period (Jan-June 2020, period 2). We determined the median and the interquartile range (IQR) of the monthly volume of HbA1c testing. We also determined the median and IQR of the percentage of abnormal HbA1c results. HbA1c results greater than 6.4% were categorized as abnormal. Point-of-care results and laboratory-based results were aggregated.

We determined the impact of the pandemic by comparing the testing volumes and the percentage of abnormal results for each month in period 1 and period 2. We calculated the percent change in testing volume, ΔV and the change in abnormal results, ΔA for each month at each location (change was calculated relative to the corresponding month in 2019). We also calculated the median percentage change in volume, ΔV_m and median percentage change in the number of abnormal results, ΔA_m over all locations. We calculated these statistics (ΔV_m and ΔA_m) for three cohorts: all patients, inpatients and outpatients.

Data from all sites were aggregated and five-point summaries were calculated (minimum, 25th percentile, median, 75th percentile, maximum) for each statistic by month for each patient cohort. The monthly change was visualized by creating box plots of the percent change in volume and abnormal results by month. We also tested for a relationship between ΔV and ΔA using hierarchical regression with location as a random effect and plotted the relationship between ΔV and ΔA for each site (the slope and intercept were both modeled as random effects).

We also compared the change in testing volume for HbA1c with the change in total testing (exclusive of Covid-19 testing) at ARUP and at the University of Utah hospital laboratory. ARUP is a national reference laboratory that performs testing for hospitals across 50 states. Testing volume for ARUP was selected as an indicator of testing nationally. The study was limited to adults aged 18 to 70. We determined the sex and age distribution of outpatients who received HbA1c testing.

3. Results

Characteristics of Participating Institutions: Eleven institutions participated in the study (Table 2). The institutions were dispersed geographically across the US (N = 9) and Canada (N = 2), the median monthly volume of HbA1c testing in period 1 was 4968 (IQR: 3137 – 10929) for all patients, 826 for inpatients (IQR: 366-1181), and 3057 (IQR: 2256 – 9768) for outpatients. The median percentage of abnormal HbA1c results was 38% (IQR: 32–44) for all patients, 41% (IQR: 36 – 46) for inpatients, and 35% (IQR: 29 – 44) for outpatients.

Impact of Shutdown on Overall Testing at ARUP and the University of Utah. The relative testing volume at ARUP and at the University of Utah increased slightly in January and February but decreased in March through May (Fig. 1). Similar results were seen for 25-OH vitamin D, basic metabolic profile, and complete metabolic profile (Supplementary Figs. 1 and 2).

Demographics of Tested Outpatients at the University of Utah: Forty-two percent of the tested population was male. Ages were evenly distributed and demonstrated little variation by year (Table 1).

Impact of Shutdown on HbA1c Testing Volume and Abnormal Results. Across all participating institutions, the volume of HbA1c testing for all patients increased by about 16% in 2020 relative to 2019 over the months of January and February (Fig. 2, Supplemental Table 1). Testing volumes decreased in March, April and May by 23, 61 and 40% relative to the corresponding months in 2019 but increased by 2% in June. There was little change in the frequency of abnormal results over the first three months of 2020 (ΔA_m = 2, −1 and −4%); however, the frequency of abnormal tests increased by about 19% in April and May, and returned to baseline in June (ΔA_m = 2%).

The volume of HbA1c testing for inpatients increased by about 7% in

Table 1
Demographics of Tested Outpatients at University of Utah Hospital Laboratory. The cell entries represent the percentage in each category. For example, in January 2019, 45% of those were tested were male and 13% of all patients (male and female) were between 19 and 30 (inclusive).

Year	Month	Male	Age Range				
			19–30	31–40	41–50	51–60	61–70
2019	Jan	45	13	18	18	19	18
	Feb	44	14	19	18	19	17
	Mar	44	14	18	18	19	18
	Apr	43	15	19	18	17	18
	May	44	14	18	19	18	18
	Jun	45	13	19	19	19	17
	Average	44	14	19	18	18	18
2020	Jan	43	15	19	19	19	16
	Feb	43	16	20	18	18	15
	Mar	44	16	20	17	18	17
	Apr	40	20	21	14	16	17
	May	43	14	17	16	17	20
	Jun	44	12	19	16	18	19
	Average	43	16	19	17	18	17

Table 2
Characteristics of participating institutions.

Institution	Baseline HbA1c Testing (2019 average)	
	Monthly Volume	Percent Abnormal
University of Saskatchewan	12,202	31
University of Utah	5623	15
University of CA, San Francisco	3237	30
Los Angeles County, USC Medical Center	3320	41
McMaster University	262	41
University of Iowa	2852	36
Kaiser Permanente, Washington	11,588	34
Geisinger	15,372	50
Washington University, Saint Louis	3037	33
University of Texas Southwestern Medical Branch	4968	57
University of Pennsylvania	10,270	43

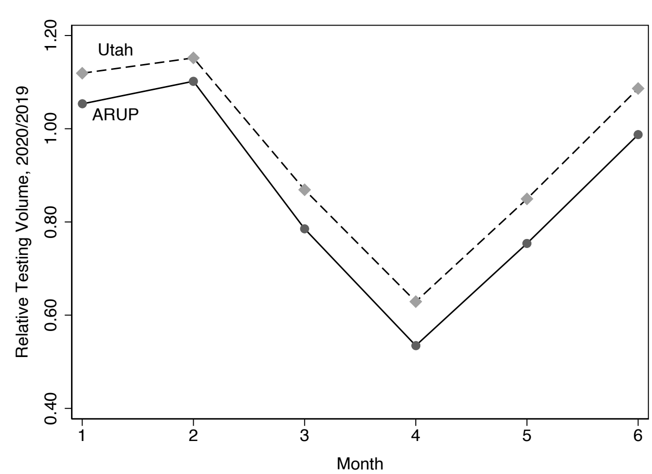

Fig. 1. Change in Relative Testing Volume by Month. The figure shows the ratio of total testing (2020/2019) for ARUP and the University of Utah hospital laboratory. Covid testing was excluded.

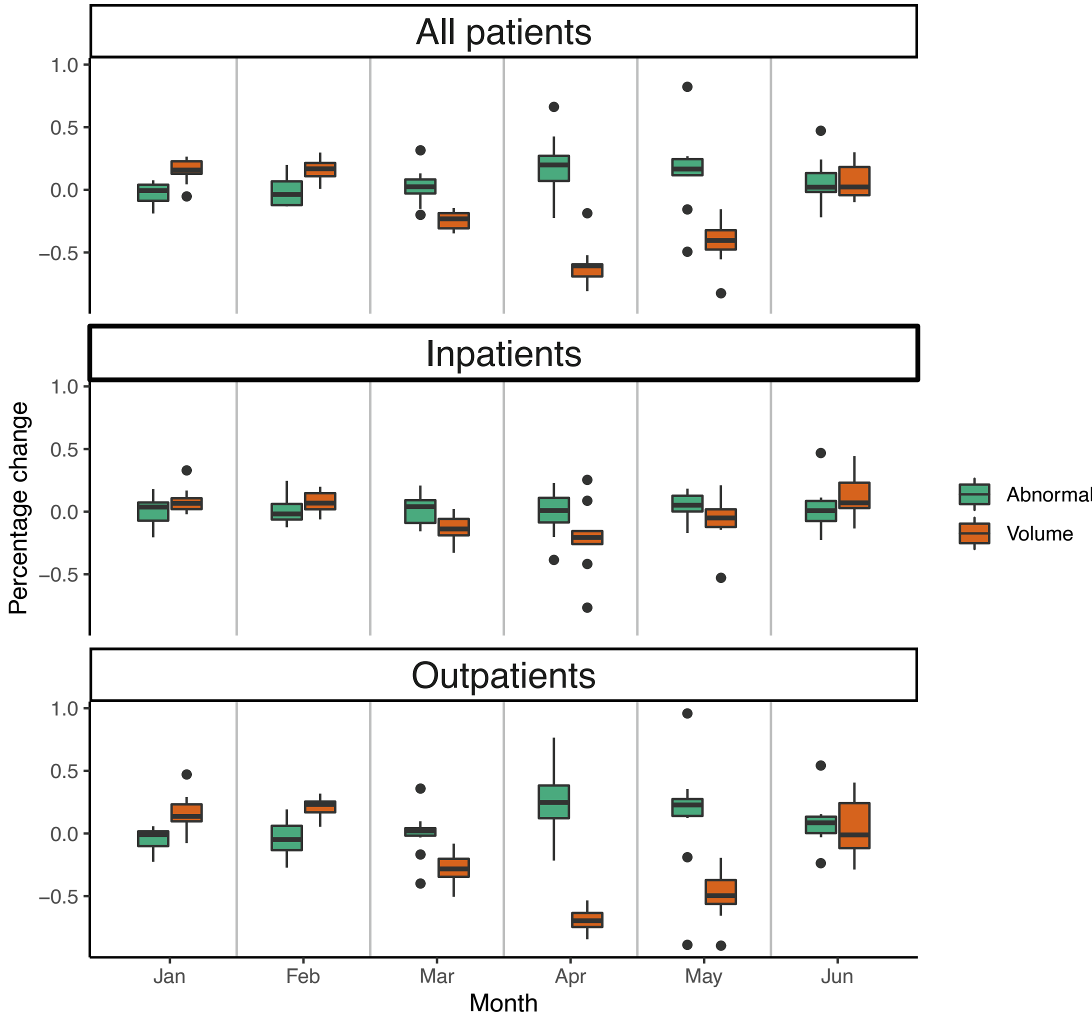

Fig. 2. Change in the Relative Testing Volume and Relative Percentage of Abnormal HbA1c Results by Month. Relative change was measured as 2020 results relative to 2019. HbA1c results greater than 6.4% were categorized as abnormal. Each month represents results from 11 sites. The white line in the box indicates the median and the length of the box indicates the interquartile range. Dots indicate outliers. Numerical values corresponding to the figure are detailed in supplemental Table 1.

January and February, decreased by approximately 17% during March and April, and recovered to 2019 levels in May and June (ΔV_m = -5 and 7%) (Fig. 2). The percentage of abnormal results showed little change in 2020 relative to 2019. The percent change of abnormal results ranged from a decrease of 2% to an increase of 5%.

The volume of HbA1c testing for outpatients increased by 14 and 23% in January and February, decreased 28, 70 and 50% March to May, and recovered to 2019 levels in June. The percentage of abnormal results was similar to 2019 in January to March of 2020 (ΔA_m = -1, −5, and 2) but increased in April, May and June (ΔA_m = 25, 24, 9%)

We tested for a relationship between the percent change in testing volume (ΔV) and the percent change in abnormal HbA1c results (ΔA) among outpatients Ten of 11 locations showed a negative relationship between testing volume and abnormal HbA1c result frequency (Fig. 3). The relationship varied by site. For example, at one site there was a 0.85% decrease in abnormal results for every one percent increase in testing volume. At another site, there was a 0.09% increase in abnormal results for every one percent increase in testing volume. On average, we found that the ΔA decreased by 0.31% for every 1% increase in ΔV ($p < 0.0005$). That is, decreases in testing volume were associated with an increase in the frequency of abnormal results.

4. Discussion

The COVID-19 pandemic brought with it the harsh reality that outpatient care for people with diabetes mellitus was not equipped for remote monitoring. The data show that testing for the quintessential 'standard of care' measurement for glycemic control (HbA1c) was decreased up to 70% during the height of shutdown (April 2020) suggesting that many patients went without formal assessment of glycemic control for at least 3–4 months. This could have been prevented.

The current recommendation is to monitor the HbA1c every 3 months in patients with diabetes mellitus (depending on prior glycemic control), annual screening in adults with prediabetes and screening at least every 3 years in adults over the age of 65 years and adults who are overweight/obese with at least one risk factor [6]. This is a large group and encompasses a significant portion of people receiving primary care and endocrinology outpatient clinics. The recommendation of monitoring HbA1c quarterly is based on prior data showing that decreased testing is associated with a 1.5% increase in HbA1c (i.e., worse glycemic control), whereas frequent monitoring was associated with a 3.8% decrease in HbA1c (i.e. improved glycemic control) [7]. Given the prolonged trajectory of the pandemic, continued lack of testing may result in worsening of glycemic control which can eventually result in worsened health outcomes in those with diabetes mellitus [8], and in a

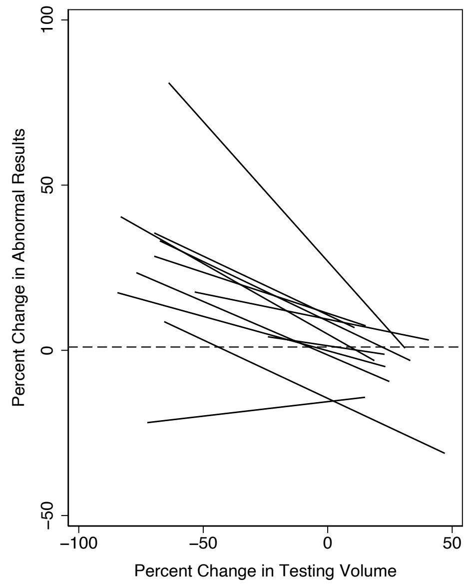

Fig. 3. Relationship between the Relative Testing Volume and Relative Percentage of Abnormal Results (2020 relative to 2019) for Outpatients by Location. Each line shows the relationship between the percentage change in abnormal results, ΔA, and the percentage change in HbA1c testing volume, ΔV, for one location.

delay of making a new diagnosis of diabetes mellitus which can lead to a higher incidence of diabetes mellitus in the future due to lack of early intervention measures [9]. Indeed, the decreased testing was not only seen in the care of diabetes mellitus but across all outpatient specialties [10,11].

While the outpatient HbA1c testing volume was significantly lower, the inpatient HbA1c testing volume did not change significantly. Other authors noted decreased acute surgical [12] and cardiac complaints [13], similar hip fracture frequencies [14] and increased adult psychiatric admissions [15]. In one of the largest cohorts from New York focusing on the comorbidities of hospitalized patients with COVID-19, diabetes mellitus was the third most common comorbidity (33.8%) after hypertension (56.6%) and obesity (41.7%). It is likely that the lack of change of inpatient HbA1c testing during the shutdown months were due to increased inpatient management of people with diabetes mellitus.

Once the switch to telehealth was made, the outpatient volumes increased and then a delayed increase in HbA1c testing volume was seen in May with a return to normal in June 2020. Medical video communication has been used since 1959 [16] yet, by January 2020, it still had not been widely utilized by the medical community. Multiple studies have shown improved glycemic control with telehealth [17-19]. Reimbursement, however, has historically prevented its use and thus created a barrier for most institutions across the country [20]. The pandemic brought with it a lift to these barriers, allowing telehealth to take its rightful place in diabetes management. In patients with a diagnosis of diabetes mellitus, cloud-based platforms for remote monitoring of glucose meters, continuous glucose monitors and insulin pumps are more easily accessible than in the past. In fact, the information from these devices can be more valuable than the actual HbA1c because they reveal continuous results rather than a longitudinal average. The Australian government recognized this and moved swiftly to ensure people with diabetes mellitus had access to these technologies during the pandemic [21]. The use of home HbA1c monitoring [22] and urine albumin testing [23] are also available. Mobile phlebotomy units can be accessed for other necessary lab draws. Data sharing between electronic medical record systems and clinical laboratories would be the final step to close the loop ensuring a complete virtual visit. If these systems are in place, access to care would be available for much of the population.

This study has several limitations. The study only covered a single test. A survey of a broader range of tests could have provided more insight into the impact of Covid-19; however, for clarity and for logistical reasons, we decided to limit the study to HbA1c. We selected HbA1c because it is an important test that affects a large population and has a widely accepted reference limit for abnormal results. We found that the decrease in HbA1c testing during the early phase of the pandemic was consistent with the pattern of total testing performed at a national reference laboratory and with the pattern of testing at a university hospital laboratory. Thus, the decrease in laboratory testing was widespread and was not isolated to HbA1c.

We did not collect data on subpopulations such as type I or type II diabetes, pediatric patients, or explore the underlying reason for the HbA1c test (e.g., diagnosis, annual exam, follow-up). While these data would provide additional insight, our objective was to identify broad patterns across multiple institutions. Collecting such data could be possible in a single institution but would have been challenging to collect across multiple institutions. We did not include the pediatric population which could account for a large portion of tests. It is possible that results differ for the pediatric population. Despite this, we believe our results show the impact of reduced access to testing on an important population.

The objective of the study was to identify broad patterns in testing volume and in abnormal results. Consequently, we did not perform a longitudinal analysis by patient to look for detailed patterns in testing. We assumed that testing would be approximately uniformly distributed over time and, for that reason, it was sufficient to compare aggregate results beginning in Jan 2019.

The most important strength of this study is the broad sampling across the United States and Canada. In addition, the relationship between the testing volume and the frequency of abnormal results was consistent in 91% of centers (10/11). The data reflect sampling from people who accessed care and are therefore at risk to selection and/or convenience bias. The parameters measured were volume of HbA1c testing and therefore further conclusions beyond those mentioned are unable to be drawn. Underlying characteristics of the individuals who were tested and why they did get tested are unknown. In particular, we were unable to distinguish between tests performed for screening, diagnosis and monitoring.

The COVID-19 pandemic brought with it a major disruption to outpatient care. This highlighted a significant deficit in glycemic monitoring by traditional measures (HbA1c). It also brought to light the benefits of telehealth. As we look ahead, outpatient diabetes care teams should shift gears and focus on education and implementation of the available technologies to perform effective, complete virtual care. Telehealth can fill the gap in traditional care models and prevent disruption to standard of care whenever the next pandemic strikes.

CRediT authorship contribution statement

Anu Sharma: Writing - original draft, Writing - review & editing. **Dina N. Greene:** Conceptualization, Methodology, Investigation, Writing - review & editing. **Allison B. Chambliss:** Investigation, Writing - review & editing. **Christopher W. Farnsworth:** Investigation, Writing - review & editing. **Deborah French:** Investigation, Writing - review & editing. **Daniel S. Herman:** Investigation, Writing - review & editing. **Peter A. Kavsak:** Investigation, Writing - review & editing. **Anna E. Merrill:** Investigation, Writing - review & editing. **Sheng-Ying (Margaret) Lo:** Investigation, Writing - review & editing. **Martha E. Lyon:** Investigation, Writing - review & editing. **Gabrielle Winston-McPherson:** Methodology, Investigation, Writing - review & editing. **Lauren N. Pearson:** Conceptualization, Methodology, Investigation, Writing - review & editing. **Jeffrey A. SoRelle:** Investigation, Writing - review & editing. **Avantika C. Waring:** Investigation, Writing - original draft, Writing - review & editing. **Robert L. Schmidt:** Conceptualization, Methodology, Formal analysis, Writing - original draft, Writing -

review & editing.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cca.2021.04.018.

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