

Feasibility of Using Cumulative Red Blood Cell Parameters as a Quality Control Tool During a Pandemic: Insights from the COVID-19 Pandemic

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Abstract. The COVID-19 pandemic affected every section in healthcare including laboratories. Commercial quality control materials were very costly or not available during pandemic even to the Ministry of Health Sri Lanka. Daily cumulative means of laboratory results were recommended as an alternative and effective quality control measure. Yet laboratories did not use this method due to the fear of influence of Covid related changes in test results. This study aimed to determine the plausibility of using cumulative means of red blood cell parameters as reliable internal quality control tools during a pandemic. This retrospective observational study was conducted in a large private sector hospital laboratory in Galle during the pandemic. Monthly cumulative means were calculated for key red cell parameters; RBC, Hb, MCV, MCH, and PCV in the years 2018, 2020, and 2021 using complete blood count reports in patient databases. Cumulative means in 2018 were considered the standard baseline. Monthly cumulative means for 2020 and 2021 were plotted and compared with those of 2018. Total of 14,291, 21,259, and 27,210 CBC reports were collected in years 2018, 2020, and 2021, respectively. Means for RBC, Hb, MCV, MCH, and PCV in 2018 were within reference intervals. Monthly cumulative means for all red cell parameters during 2020 and 2021 fell within calculated range for 2018. Both RBC and Hb means for 2020 and 2021 were consistently above the mean of 2018, while MCV and PCV values were consistently below 2018 mean. During a pandemic like Covid-19, cumulative means of red cell parameters can serve as an effective quality monitoring tool in hematology laboratories.

Keywords. Covid-19, Cumulative means, Internal quality control, Red cell parameters

INTRODUCTION

Coronavirus disease (COVID-19) was first found in Hubei Province, China, in December 2019. Due to its rapid global spread, the World Health Organization declared COVID-19 a global health emergency in January 2020. By January 31st, 2022, Sri Lanka had recorded a total of 610,103 COVID-19 cases, with 15,420 deaths reported (1). From the time of detection of the first COVID-19 patient in the country, several measures were implemented to control the spread of the disease. These included mask-wearing in public places such as public transport and workplaces (1). Surgical masks, N95 masks, and homemade cloth masks were widely used by the general public for personal protection (2). Several studies have reported hypoxia-induced changes in blood parameters among healthy individuals wearing masks during daily activities and at workplaces (3, 4). During the COVID-19 pandemic in Sri Lanka, while symptomatic patients and their close

contacts were tested for COVID-19, asymptomatic individuals in the community were not routinely tested. However, studies have indicated a significant proportion of asymptomatic COVID-19 cases within communities (1, 5). To ensure the reliability of test results in medical laboratories, quality control is essential. Quality control includes both internal and external quality control. Internal quality control focuses on ensuring precision and repeatability of test results, while external quality control ensures accuracy. In medical laboratories, internal quality control can be established by using commercially available quality control materials, patient samples, and patient data either alone or in combination. For complete blood count tests, at least two levels of quality control materials are used to ensure the reliability of results (6). However, these commercially prepared materials have limited shelf lives, and are costly making their use a logistical and financial burden for laboratories. The use of commercial quality

control materials became more critical during the COVID-19 pandemic, when a nationwide disruption in the supply of commercial quality control materials led to a shortage of commercial quality control materials for nearly about a year and the cost of the available materials became very high. Daily cumulative means of laboratory test results are recommended as an effective tool for internal quality control. Cumulative means is a long-term estimate of a performance precision of a method based on a large number of control measurements collected over a long period of time. These cumulative means can be used to analyze trends, deviations, and patterns in how each parameter varies over time. This approach is particularly suitable for large community hospital laboratories with high daily patient turnover. Typically, cumulative means stay within a specific range unless there is a significant shift in the characteristics of the patient population being tested. However, there was a doubt among laboratory professionals on possible shift of patient results due to the presence of undiagnosed Covid patients in the community at large. To the best of our knowledge, no studies have explored the feasibility of using cumulative means of red cell parameters as quality control tools in laboratories during an epidemic (or pandemic). This study aimed to find the monthly cumulative means of red blood cell parameters from automated complete blood count reports during the COVID-19 pandemic. The goal was to evaluate whether patient data could still serve as reliable internal quality control tools under these circumstances.

MATERIALS AND METHODS

This retrospective observational study was conducted in a large private sector hospital in Galle that did not provide inpatient care for COVID-19 patients during the pandemic. Ethical approval for the study was obtained from the Ethics Review Committee of the Faculty of Allied Health Sciences, University of Ruhuna (Reference No: 126.07.2022). Permission to access the CBC database was granted by the hospital laboratory administration. Complete blood count reports in three years—2018, 2020, and 2021—were obtained from the hospital laboratory's patient database. The year 2019 was excluded as there was no definite evidence

of COVID-19 spread in Sri Lanka during that period. Patients under 12 years of age were excluded from the study. Data on red blood cell count (RBC), haemoglobin (Hb), mean cell volume (MCV), mean corpuscular haemoglobin (MCH), and packed cell volume (PCV) were extracted for analysis. Monthly cumulative means and standard deviations were calculated for RBC, Hb, MCV, MCH, and PCV in the years 2018, 2020, and 2021. The cumulative means and standard deviations for these red cell parameters in 2018 were used as the laboratory's target and the range based on the standard practice. The monthly cumulative means for 2020 and 2021 were plotted and compared with the mean for 2018. Plotted graphs of 2020 and 2021 were inspected visually to see any deviations beyond 3SD limits from the mean of 2018 and to assess any trends or shifting of cumulative data during the study period. Additionally, the monthly incidence of COVID-19 cases in the Galle District, from which the study population was drawn, was obtained from the Epidemiology Unit of the Ministry of Health. These monthly incidence data were plotted to observe the patterns of COVID-19 incidence in Galle in 2020 and 2021. During the study period the laboratory continued internal quality control using three standard methods; commercial material one level daily, duplicate test results within run, and testing retained samples between runs as it is required to sustain the ISO 15189 accreditation. External quality control was continued once in three months based on the international and national norms.

RESULTS

A total of 14,291, 21,259, and 27,210 CBC reports were collected for the years 2018, 2020, and 2021, respectively. The monthly cumulative means for RBC, Hb, MCV, MCH, and PCV in 2018 were within the normal reference intervals. The monthly cumulative means for all red cell parameters during 2020 and 2021 fell within the calculated 3SD range for 2018. Interestingly, monthly cumulative means for both the RBC and Hb during 2020 and 2021 were consistently above the mean of 2018, while those of MCV and PCV were consistently below the mean of 2018. (Figures 1 to 5).

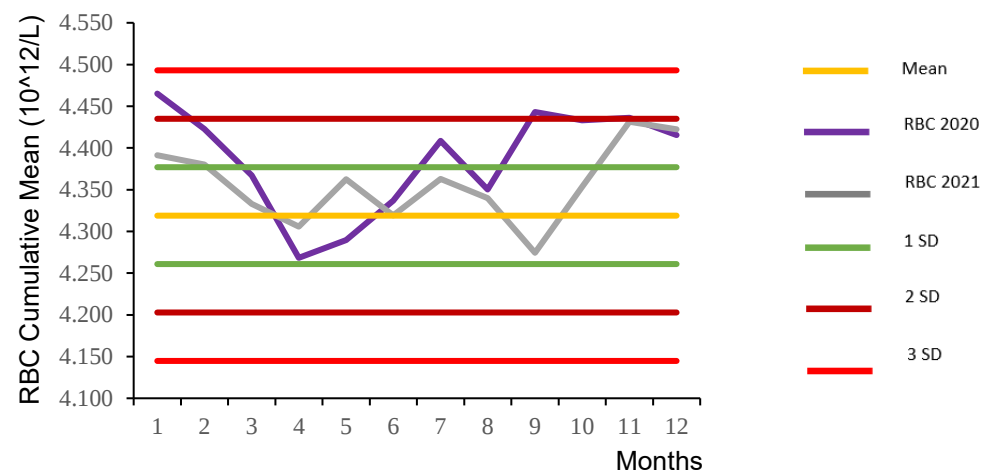


Figure 01. Monthly cumulative mean variation of red cell counts in 2020 and 2021

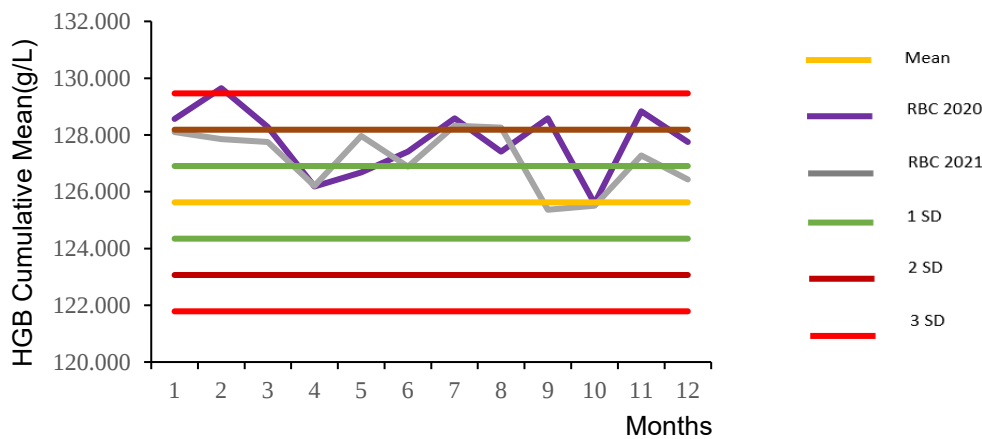


Figure 02. Monthly cumulative mean variation of haemoglobin in 2020 and 2021

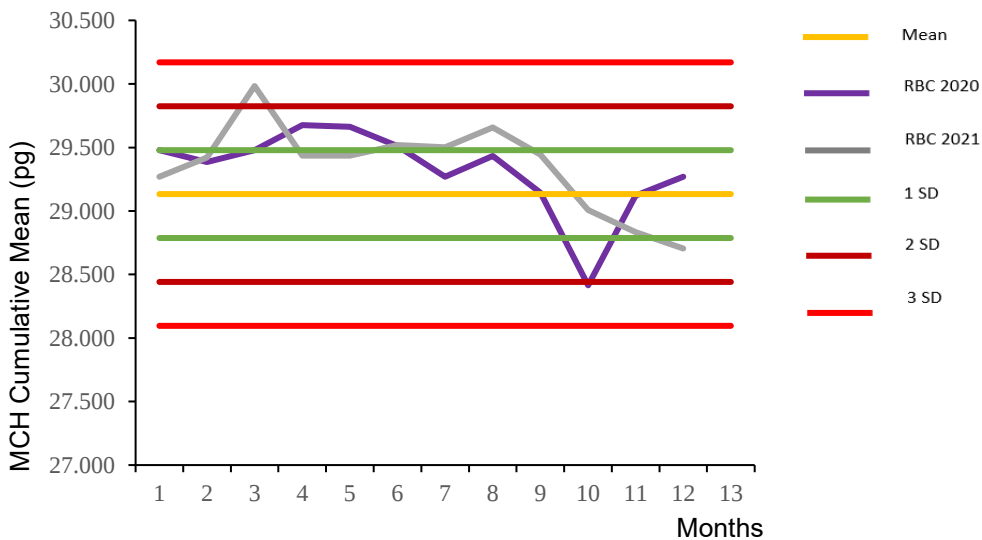


Figure 03. Monthly cumulative mean variation of mean corpuscular haemoglobin in 2020 and 2021

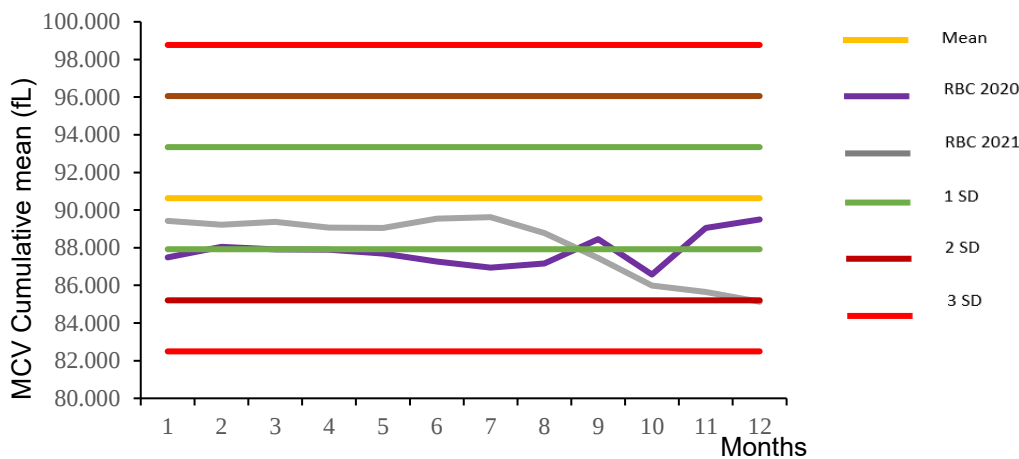


Figure 04. Monthly cumulative mean variation of mean corpuscular volume in 2020 and 2021

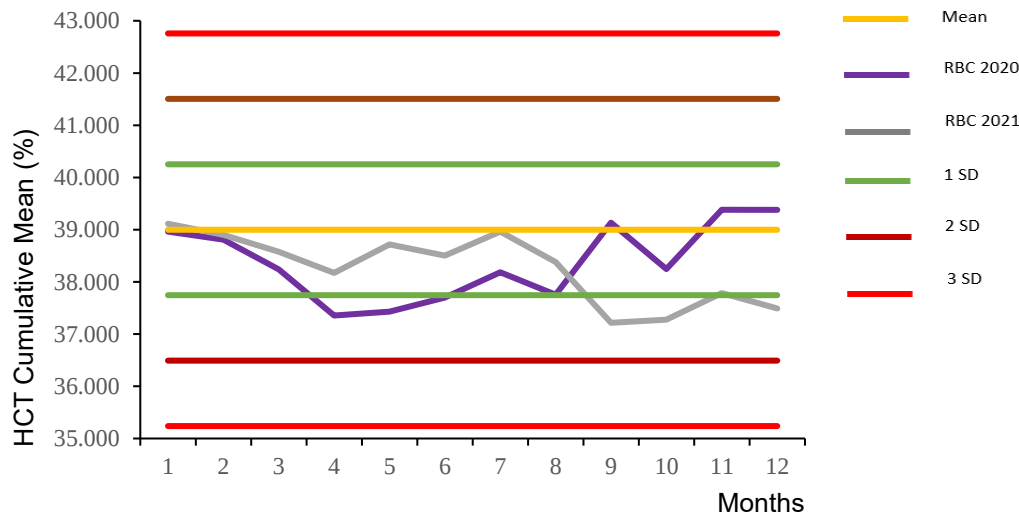


Figure 05. Monthly cumulative mean variation of haematocrit (Packed cell volume) in 2020 and 2021

The graph plotted to see the distribution of Covid cases in Galle in the years 2020 and

2021 showed increasing number of cases between April and October in 2021 (Figure 6).

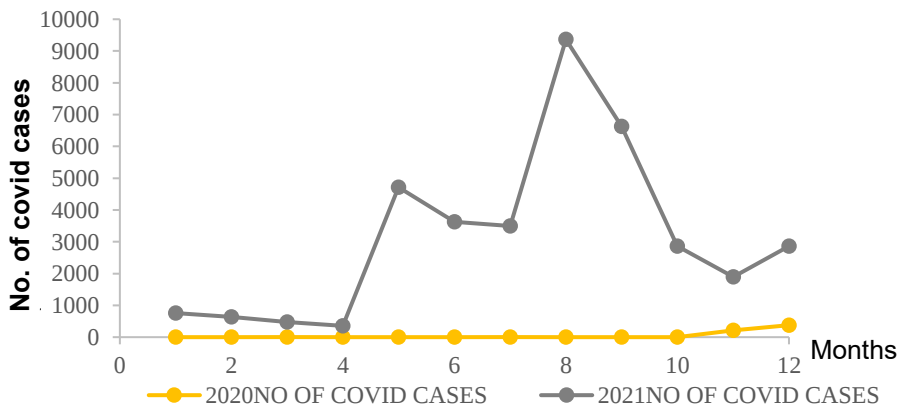


Figure 06. Covid-19 distribution in Galle district 2020 and 2021 (Data source: Epidemiology Unit of the Ministry of Health: Corona virus disease situation reports 2020, 2021)

DISCUSSION

In our study, the cumulative means of all the red cell parameters studied during the years 2020 and 2021 showed no major deviation from the set control limits which is the 3SD range defined for the year 2018. This indicates the plausibility of use of cumulative patient data as an alternative method for internal quality control method even during a pandemic of this nature. Interestingly, the cumulative means of RBC and Hb in 2020 and 2021 showed similar trends and were above the target cumulative means of 2018. Previous studies have suggested that prolonged mask-wearing may lead to intermittent hypoxia and consequent increase in haemoglobin mass (3, 4). A study conducted in Dubai to assess the blood cell parameters during the lockdown period has shown a significant increase in RBC, Hb, and PCV. They attributed these changes to increased smoking and stress during lockdown period (7). In contrast to that, another study carried out among airport workers during the COVID-19 pandemic has shown a significant decrease in RBC and Hb concentration (8). At the beginning of 2021, there was widespread panic, and a shortage of masks in Sri Lanka. Many individuals resorted to using homemade cloth masks. The use of these suboptimal quality masks causing hypoxia and the stress associated with lockdown may explain the higher cumulative mean values of Hb and RBC in this patient population.

As this was a retrospective study, we were unable to obtain information on the frequency, duration, and the type of masks used by the study subjects, or on the quality of the masks. However, based on government-mandated regulations, we assumed that all citizens, particularly in major cities, adhered to the requirement of wearing masks continuously in workplaces and public spaces.

In spite of the mandatory use of masks, the stress caused by restricted movement, and potentially undiagnosed cases at large in the community, our study found that red cell parameters consistently remained within the

laboratory's defined target range, even during the peak of COVID-19 infections in the region.

Although use of cumulative data as an internal quality control method does not require additional cost, it has not been widely used by many laboratories as a quality control tool largely due to concerns on potential influences of patient variables. This study shows that cumulative data remains unaffected even during a pandemic of this nature, with values consistently falling within the 3SD range of the target mean suggesting that using readily available cumulative data is cost-effective and dependable as a quality control tool in a laboratory with high patient turnover but not with low patient turnover.

Furthermore, the prolonged mandatory use of masks, including substandard ones, during the pandemic was not adequately studied as a potential health concern. While we observed higher cumulative mean values of RBC and Hb in this population during the pandemic, we were unable to assess these changes objectively at the time. The findings of this study highlight the importance of monitoring cumulative patient data during pandemics or epidemics to evaluate its potential impact on community health as well.

Conclusion

During pandemics like Covid-19, the cumulative means of red cell parameters can serve as an effective internal quality control tool in hematology laboratories. In addition, we recommend future studies to analyse the possibility of use of cumulative data obtained from community hospital laboratories in regions affected by epidemics or pandemics to assess the burden or issues related to preventive strategies.

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