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Quantitative Study on the Impact of Holding Duration on Unfiltered FFP Composition

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Abstract

Ensuring the safety and quality of transfusion products is a cornerstone of transfusion medicine. The presence of leucocytes in blood components can lead to adverse reactions and increase the likelihood of transfusion-related complications, highlighting the importance of minimizing their content prior to transfusion. Elevated leucocyte levels have been detected in unfiltered fresh frozen plasma (FFP) units prepared from whole blood processed after a short holding time (SHT) – the interval between blood collection and component separation. Protein concentration, another crucial indicator of plasma quality, must also be maintained within acceptable limits. In this study, 100 non-filtered FFP units processed after SHT were compared with 100 units processed following an overnight, long holding time (LHT). Unit volumes, residual leucocyte counts (RLC), and protein concentrations (PC) were measured and statistically analysed. Results demonstrated that longer holding times were associated with significantly lower RLC and higher PC. Statistical process control (SPC) analysis revealed that the SHT process was borderline to incapable of maintaining consistent product quality, even after outlier adjustments. These findings indicate that shorter holding times may compromise plasma uniformity and quality. Therefore, revising the minimum holding time is advisable to achieve optimal leucocyte reduction and protein preservation in FFP.

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Keywords: Fresh frozen plasma, holding time, residual leucocytes, plasma proteins, leukoreduction, transfusion safety

INTRODUCTION

Therapeutic efficacy and patient safety are very important aspects of transfusion. The therapeutic value of fresh frozen plasma (FFP) is mostly determined by its protein content, especially coagulation factors. Following recommendations like those established by the European Directorate for the Quality of Medicines & HealthCare (EDQM), patient safety is primarily guaranteed by removing pathogens from the unit using phagocytosis or pathogen inactivation techniques and reducing the remaining leucocyte count to a minimum [1]. Numerous elements and procedures during the blood product manufacturing process can affect the product's ultimate quality and, consequently, its safety and therapeutic effectiveness. Holding time, or the interval between whole blood collection and product separation, is one of these variables (Yousif, Sammut et al., 2025) [2]. Leucocytes can phagocytose any bacteria present during this time, as well as degrade and

inactivate them, reducing the risk of immunological reactions and infection transmission linked to transfusions. Holding time has its benefits but also has its downside. In the case of plasma, long holding times have been found to increase the degradation of coagulation factors necessary for patients receiving FFP transfusion, particularly Factor VIII which is the most labile. To balance the residual leucocyte count (RLC) and total protein concentration (PC), the appropriate holding time is, therefore, essential [2–6]. This has brought attention to how crucial it is to investigate the relationship between holding time and various parameters, such as RLC and total PC, which have not received much attention, particularly in relation to RLCs in plasma. This relationship, if it exists, can be found and examined further by comparing units with Short Holding Time (SHT) and Long Holding Time (LHT). This will help determine whether standard protocols need to be reexamined to improve the safety, efficacy, and clinical use of FFP [2].

METHODOLOGY

Experimental Design

Donations from anonymous blood donors were collected at the donation centre. Following a brief holding period of approximately three hours, 100 FFP units were processed and tested for RLC and PC. For comparison, data from a further 100 units processed following an overnight holding period were acquired from the quality control lab. Figure 1 summarizes the study design. All units' volumes were noted.

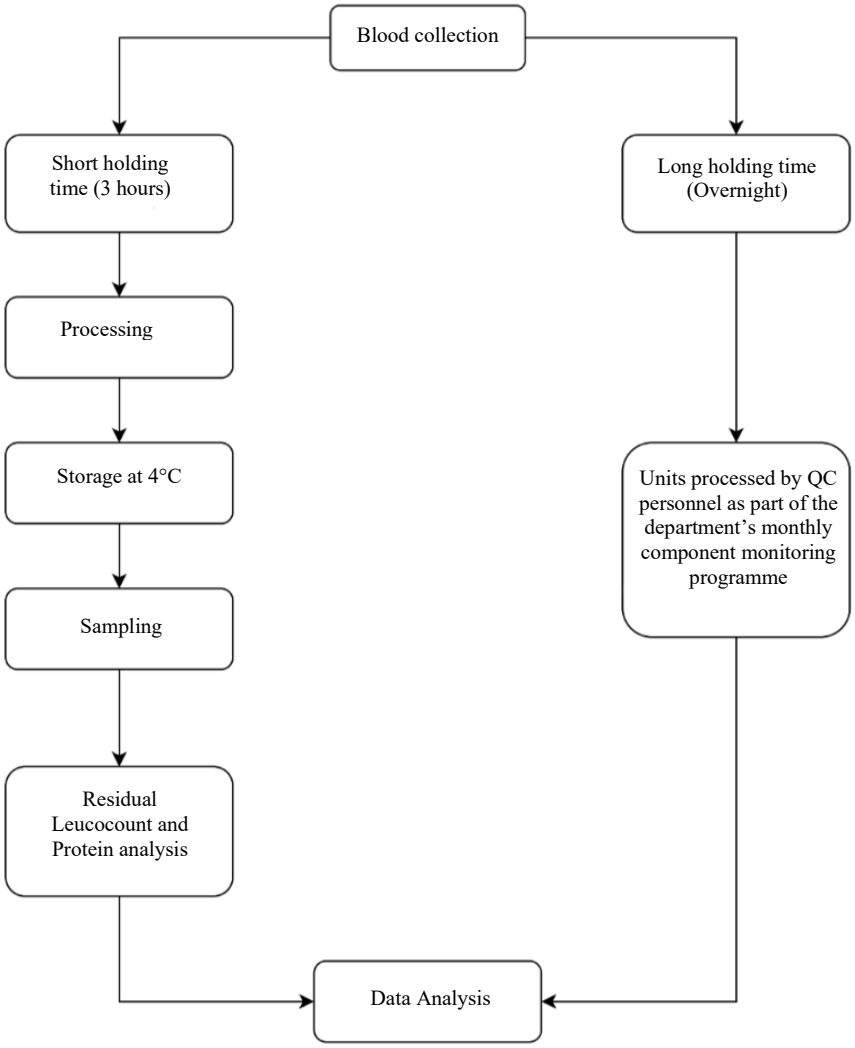

Figure 1. Experimental design.

Sample Preparation and Analysis

Plasma bags processed the previous day were weighed and volumes were calculated after correcting for bag weight and plasma density. Standard protocols were followed for mixing the units, and sterile syringes were used to aspirate the plasma. Aliquots were moved to glass tubes for leucocyte counting and to clot-activator vacutainers for protein analysis (which were sent to an outside lab for analysis). The FACSCantoTM II flow cytometer and the BD LeucocountTM Kit were used to measure the number of leucocytes. As directed by the manufacturer, counts were measured and reported as absolute leucocyte concentration ($\times 10^9$/L).

DATA ANALYSIS

Statistical Analysis

Data were organized in Excel and analysed using SPSS (Version 29.0). Descriptive statistics (mean, standard deviation) were calculated for RLC and total PC. Z-scores were used to identify outliers; values greater than ±3 were deemed extreme. The Shapiro–Wilk test was used to determine whether the distributions were normal. The Mann–Whitney U test was used to compare the means of the cohorts in RLC data, which were not normally distributed. Only descriptive statistics (mean and SD) were obtained using independent-samples t-tests. PC data was distributed normally. The independent-samples t-test was used to compare means after Levene's test was used to evaluate equality of variances. Throughout, a significance threshold of $p < 0.05$ was used.

Statistical Process Control

In addition to statistical analyses, statistical process control (SPC) was applied to assess whether the holding time procedure was stable and within control. SPC monitors variation in a process over time and identifies deviations requiring corrective action, thereby ensuring consistent product quality. Criticality levels were allocated to parameters based on process capability, with classification based on the possible influence on patient safety and product efficacy (Figure 2). To ascertain whether the procedure was capable, borderline, or incapable, the process capability index was then computed. RLC and PC are one-sided parameters (only an upper or lower limit), so the process capability index (Cpk) was used to assess process capability. Table 1 shows how Cpk values, parameter criticality, and SPC results relate to one another.

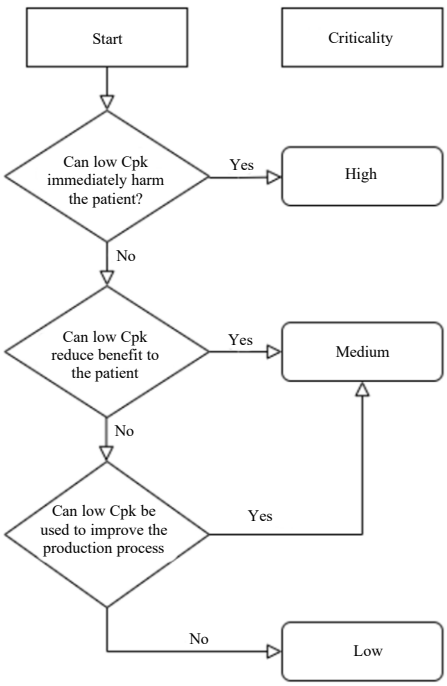

Figure 2. Criticality classification (adapted from Beckman et al. [7]).

Table 1. Determining Cpk bandings from criticality and Cpk measurements.

Specification type	Cpk values						
Two sided	>1.47	1.30–1.46	1.10–1.29	0.86–1.09	0.54–0.85	0.39–0.53	<0.39
One sided	>1.40	1.23–1.39	1.03–1.22	0.77–1.02	0.43–0.76	0.21–0.42	<0.21

Source: Adopted from Beckman [7].

Results

Data were organized by parameter and holding time. 100 FFP units made up each of the SHT and LHT holding time cohorts. Six groups were created by evaluating plasma volume, RLC, and PC; these groups were SHT volume, LHT volume, SHT RLC, LHT RLC, SHT PC, and LHT PC.

The Shapiro–Wilk test was used to assess the distributions' normality; this test is suitable for sample sizes under 300, like the ones used in this investigation.

Volume

The mean volume between the two holding time cohorts was calculated and compared. As shown in Table 2 the SHT cohort had a lower mean unit volume of 276 ml, whilst that of the LHT cohort was 283 ml, with a difference of 7 ml.

Table 2. Mean volumes and standard deviation.

	N	Mean FFP unit volume (mL)	Standard deviation
SHT	100	276	13.706
LHT	100	283	13.176

Note: Legend: FFP – Fresh frozen plasma, SHT – short holding time, LHT – long holding time.

Table 3 displays the normality test results for the volume parameter of the SHT and LHT cohorts. The SHT cohort's final p-value was 0.179. The set of volumes for this cohort was found to follow a normal distribution since this was greater than the 0.05 level of significance, supporting the null hypothesis, which postulated a normal data distribution. The LHT cohort's p-value was 0.043, which was slightly below the 0.05 threshold and suggested that the volumes in this cohort were not distributed normally.

Table 3. Test of normality.

	Shapiro–Wilk		
	Statistic	df	p-value
SHT	0.982	100	0.179
LHT	0.974	100	0.043

Note: Legend: SHT stands for short holding time; LHT for long holding time; FFP for fresh frozen plasma.

Residual Leucocyte Counts

As shown in Table 4, the mean RLC of units with a SHT was more than double that of those within the LHT cohort. However, both means were still below the maximum acceptable value of $0.1x10^9$ cells/L according to the EDQM.

Table 4. Descriptive statistics.

	N	Mean RLC ($x10^9$/L)	Standard Deviation
SHT	100	0.029	0.040
LHT	100	0.013	0.013

Note: Legend: RLC – Residual leucocyte count, SHT – short holding time, LHT – long holding time.

Figures 3 and 4 display the histograms created from the computed Z scores, which graphically illustrated the non-normal distribution of values in both cohorts. Indeed, it is clear that both graphs

exhibit a right-skewed distribution. If the Z score were substituted with the RLC of each unit, the same distribution would be seen. To differentiate between outliers that fall outside of the range of a Z score of +/–3 and statistically normal values that fall within it, a threshold of +/– 3 was established.

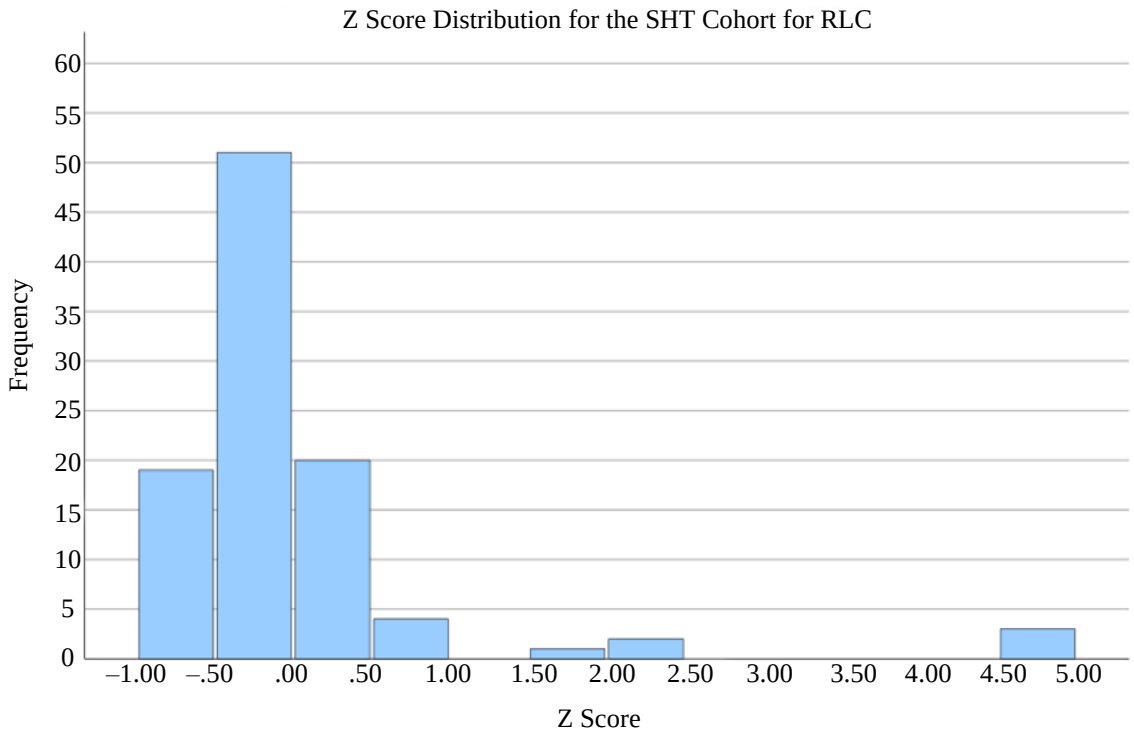

Figure 3. Z-score distribution (SHT).
Note: Legend: RLC – Residual leucocyte count, SHT – short holding time.

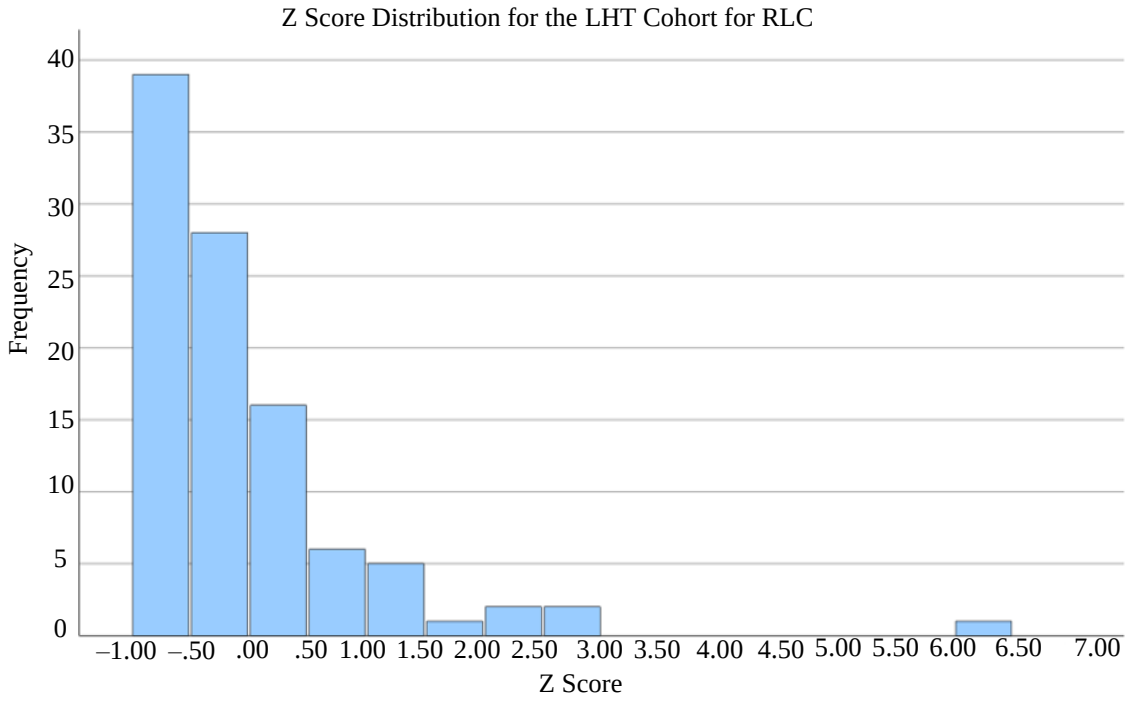

Figure 4. Z-score distribution (LHT).
Note: Legend: RLC – Residual leucocyte count, LHT – long holding time.

The probability that a Z-score exceeds the ±3 threshold by chance was determined using the NORM.S. DIST function in Excel, yielding a value of 0.0027 (0.00135 × 2), equivalent to approximately 2 in 1000. This probability corresponds to the combined area under the curve in the two tail regions beyond ±3 standard deviations, as illustrated by the unshaded sections in Figure 5.

In the current dataset, among 100 observations, 3 Z-scores (3%) for units processed with a short holding time (SHT) exceeded the threshold of ±3, identifying them as outliers. In contrast, for units processed with a long holding time (LHT), only 1 outlier (1%) was detected among 100 observations. These outliers are visible at the extreme right tails of the histograms in Figures 3 and 4, while all remaining data points fall within the acceptable Z-score range of –3 to +3.

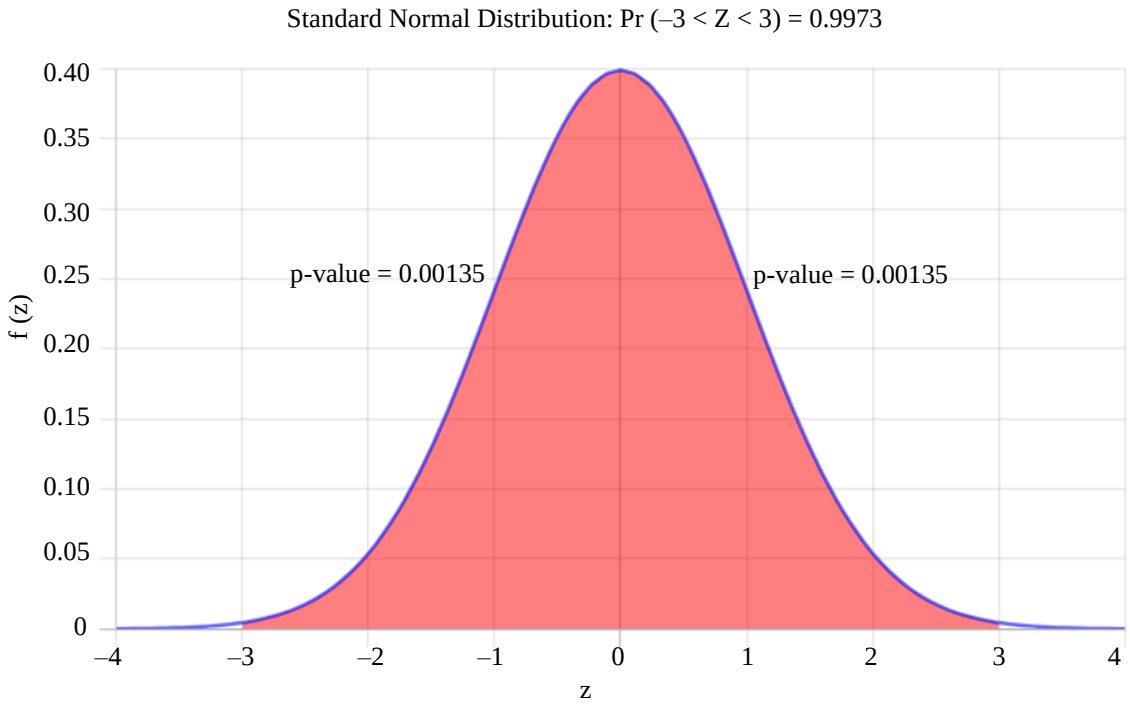

Figure 5. Normal distribution curve.

Normal distribution curve illustrates how the likelihood that a value's Z-score will be above or below a specific threshold – in this case, +/–3 – is determined. The areas that are not shaded would contain these outliers. In this instance, the total probability would be 0.0027 (0.00135 x 2) calculated by multiplying the p-value by 2 to add both ends of the curve.

The p-values for both RLC cohorts were less than 0.001 in relation to RLC, as shown in Table 5. Both cohorts had non-normal distributions, as confirmed by the rejection of the null hypothesis, which assumed a normal data distribution, because the p-values were below the 0.05 level of significance.

Table 5. Test of normality.

	Shapiro–Wilk		
	Statistic	**df**	**p-value**
SHT	0.535	100	<0.001
LHT	0.691	100	<0.001

Both cohorts' p-values were less than 0.001, which is below the significance level of 0.05 and indicates that the data distributions were not normal.

Remaining leucocyte count (RLC), short holding time (SHT), and long holding time (LHT) are the legends.

Table 6 illustrates that when comparing the two cohorts, the Mann–Whitney test also revealed a p-value of less than 0.05. Thus, in this instance, the null hypothesis – which claimed that the means differed insignificantly – was disproved. Therefore, there is a statistically significant difference between the two cohorts' means.

Table 6. Mann–Whitney test.

U-value	3058
p-value	<0.001

The two holding time cohorts' means differed significantly in terms of RLC, as indicated by the p-value of less than 0.001. RLC, or residual leucocyte count, is the legend.

The error bar graph in Figure 6 displays the 95% confidence interval for the actual mean RLC for short and long holding times, respectively. The fact that the two confidence intervals, represented by the whiskers in the figure, do not overlap, indicates that the mean RLC for units with a SHT is significantly larger than the corresponding mean RLC for the LHT cohort. The lower limit for the SHT cohort is larger than the higher limit of the LHT cohort as shown by the whiskers on the graph. It can also be noted that the SHT bar is much higher, showing that there was a wider range of values, whereas the LHT cohort had more consistent values within a smaller range.

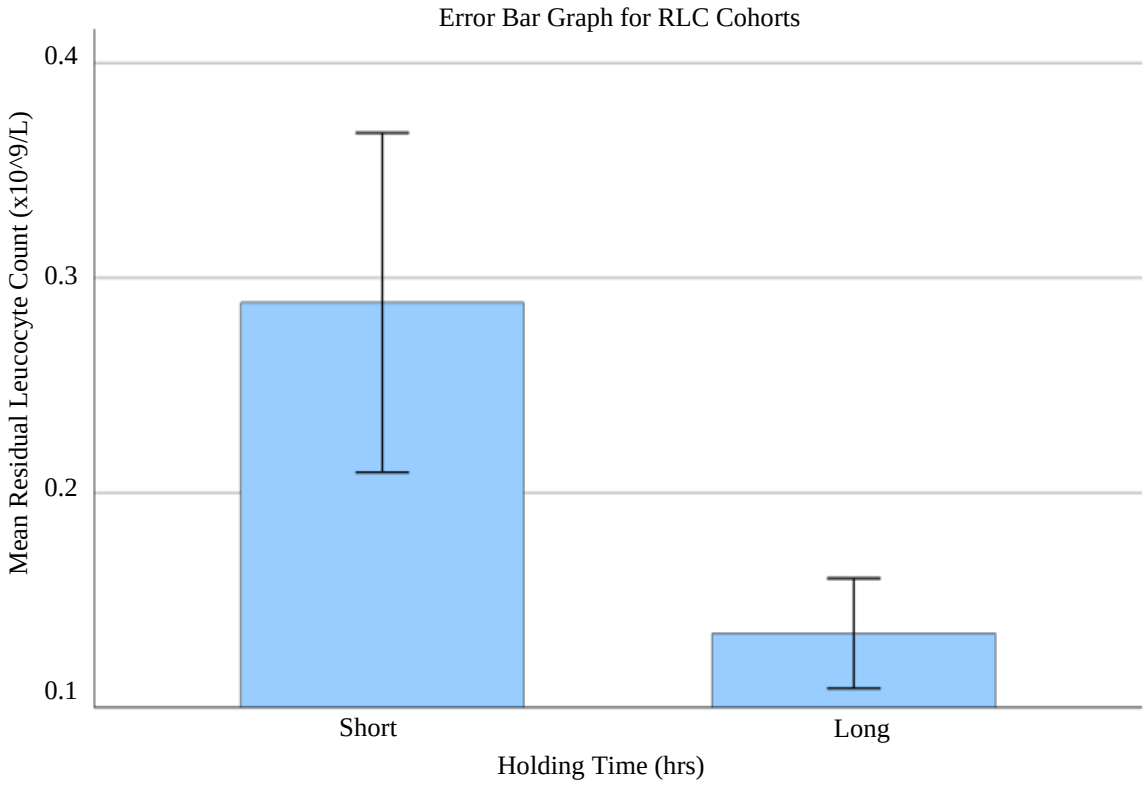

Figure 6. Error bar graph of RLC cohorts.
Note: Legend: RLC – Residual leucocyte count

This graph allows comparison of the means of two cohorts and visualises the range of values.

Protein Concentrations

From the results displayed in Table 7, it can be noted that the mean PC of the two cohorts differed by 2.03 g/L, with the LHT cohort having a higher concentration of 62.55 g/L and that of the SHT cohort being 60.52 g/L.

Table 7. Descriptive statistics.

	N	Mean PC(g/L)	Standard deviation
SHT	100	60.52	3.57
LHT	100	62.55	2.76

Note: Legend: PC – protein concentration, SHT – short holding time, LHT – long holding time.

As demonstrated by the histogram in Figure 7, the Z score values showed a normal data distribution for the SHT cohort. Figure 8 shows a less normal distribution for the LHT cohort. For both cohorts, all values were within a Z score of +/–3. The same histogram would be obtained if the Z score was to be replaced by the PC of each FFP unit.

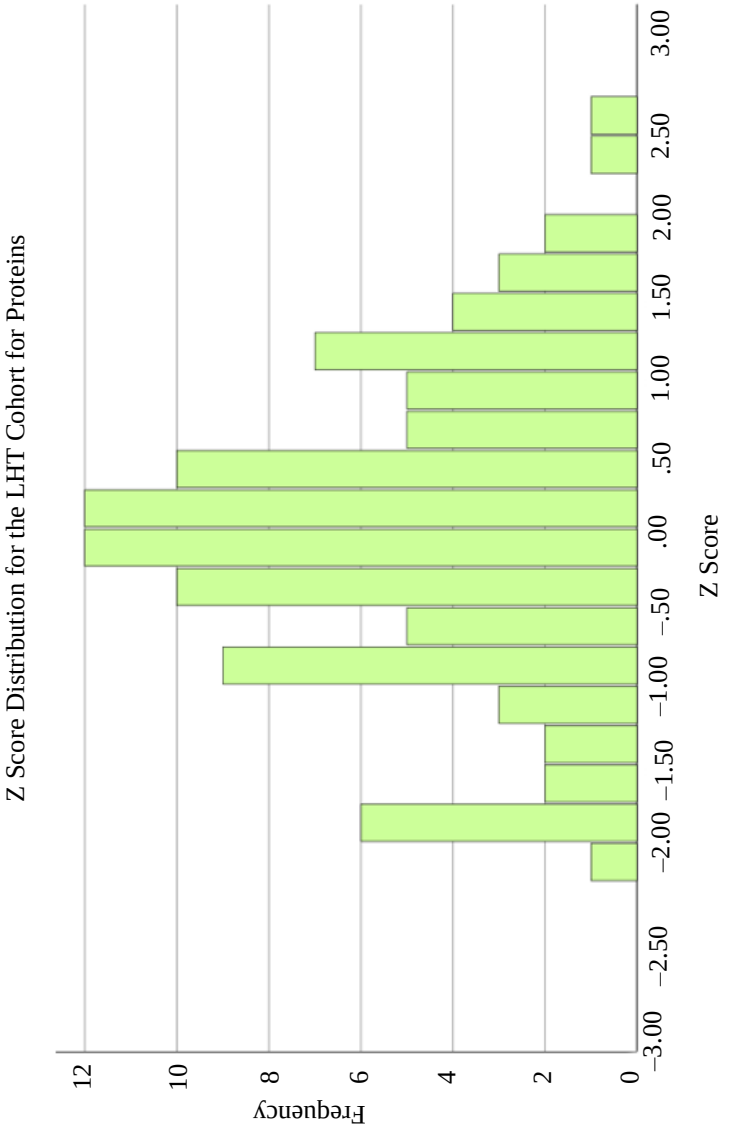

Figure 7. Distribution of Z-scores.
Note: Legend: SHT – short holding time.

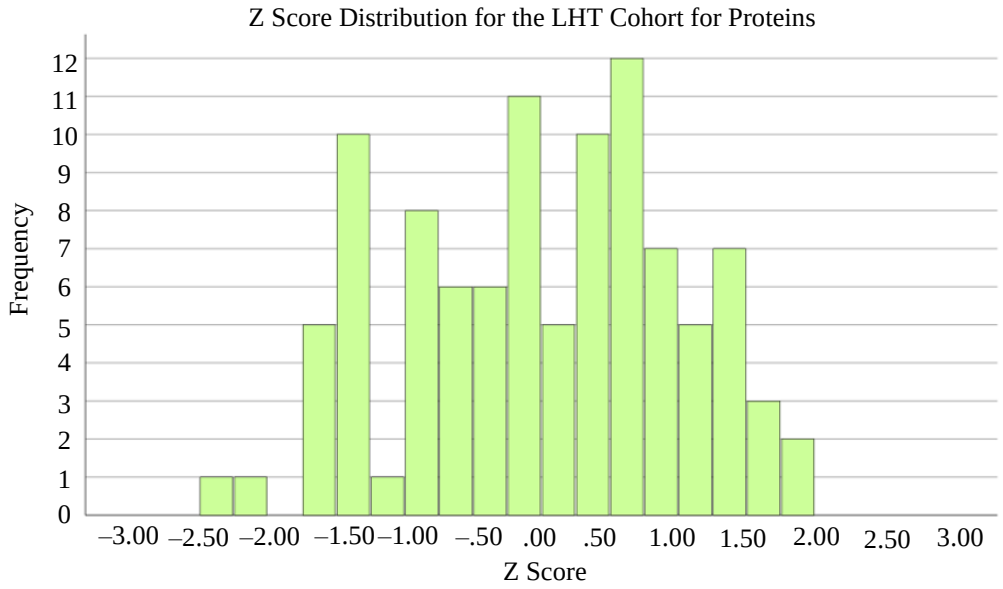

Figure 8. Distribution of Z-scores.
Note: Legend: LHT – long holding time.

Shapiro–Wilk Test for Proteins

With regards to PC, when testing normality, the p-value for the SHT cohort resulted to be 0.744. On the other hand, the p-value for the LHT cohort resulted to be 0.051 as can be seen in Table 8. Both p-values exceeded the 0.05 level of significance, and therefore, the null hypothesis which stated that the data distribution is normal was accepted for both cohorts. However, it was noted that the LHT cohort had a borderline normality since the p-value just passed the 0.05 level of significance by 0.001.

Table 8. Test of normality.

	Shapiro–Wilk		
	Statistic	**df**	**p-value**
SHT	0.991	100	0.744
LHT	0.975	100	0.051

Note: Legend: SHT – Short holding time, LHT – Long holding time

The p-value of the Levene's test for equality of variances was 0.071 (Table 9). This value is greater than the 0.05 level of significance. Therefore, the null hypothesis which stated that there is no statistical difference between the two standard deviations was accepted, indicating that the standard deviations of the two cohorts are similar.

Table 9. Levene's test.

F-value	3.287
p-value	0.071

The p-value for the independent samples T-test resulted to be less than 0.05 (<0.001), as shown in Table 10, thus the null hypothesis which stated that there is no statistical difference between the means of the two independent groups was rejected. Therefore, indicating that there is a statistical difference between the means of the two cohorts with regards to PC.

Table 10. Independent samples T-test.

T-value	4.479
p-value	<0.001

Figure 9 displays the 95% confidence interval for the actual mean PC for short and long holding times, respectively. The two confidence intervals do not overlap, indicating that the mean PC for units with a LHT is significantly larger than the corresponding mean PC for the SHT cohort. The lower limit for the LHT is larger than the higher limit of the SHT as can be seen by the whiskers on the graph. The two bars can be seen to be of similar height, showing that there was a similar range of values.

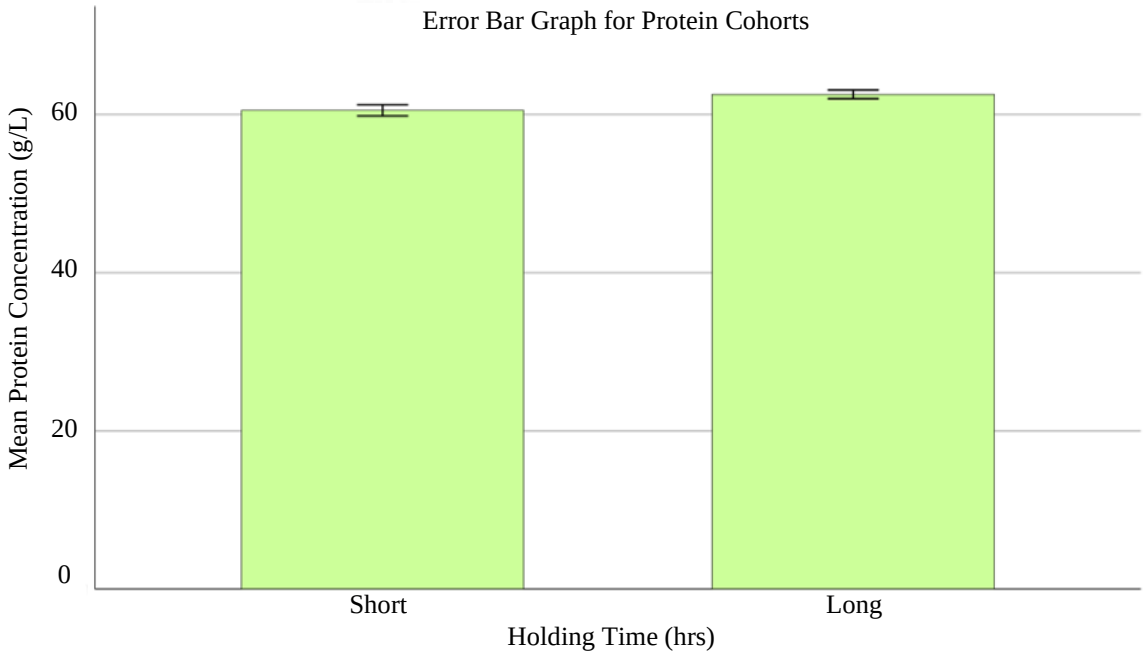

Figure 9. Error bar graph of protein cohort means.

Statistical Process Control

According to statistical process control classification, leucocytes are classified as a critical parameter since high levels put the patient in immediate harm due to the development of unwanted transfusion reactions. However, a lower dose of protein would not endanger the patient because plasma is not transfused for its total protein properties; as a result, this parameter is categorized as having a low criticality level. Because there are very few indications for plasma transfusion and the plasma product is typically used in combination with other blood components during severe blood loss or as a replacement fluid in plasma exchange therapies, the plasma volume is also regarded as having low criticality.

Using the parameter criticality and calculated Cpk values, the capability outcome could be determined. These results have been compiled in Table 11.

Table 11. SPC capabilities.

	Parameter	Criticality	Mean	SD	Cpk	Capability outcome
Short Holding Time	Volume	Low	276.17	13.71	0.68	Capable.
	Leucocytes	High	0.03	0.04	0.50	Incapable.
	Leucocytes (no OOS)	High	0.02	0.02	1.17	Borderline.
	Proteins	Low	60.52	3.57	0.98	Capable.
Long Holding Time	Volume	Low	282.72	13.18	0.71	Capable.
	Leucocytes	High	0.01	0.01	9.55	Capable.
	Proteins	Low	62.55	2.76	1.52	Capable.

The capability outcome based on the Cpk value and criticality is shown in this table along with the computed Cpk value for each cohort for unit volume, RLC, and protein concentration.

Legend: RLC stands for residual leucocyte count, OOS for out of specifications, and Cpk for capability index k/process capability index.

Also shown in Table 11, when considering the volumes of FFP units, the capability outcome was capable for both cohorts. This is also true for PC. On the other hand, the capability outcome for the RLC of units with a SHT, was incapable. The process however was capable for units with an LHT.

Out of specification (OOS) values were removed from the SHT cohort for RLC to assess the influence of outliers. When this was done, the process capability changed from incapable to borderline.

DISCUSSION

FFP is a vital transfusion product which is indicated in cases of complex coagulopathies, severe bleeding, Vitamin K deficiency, and burns amongst others. To guarantee that the product has a therapeutic effect and that any unintended negative transfusion reactions are prevented for the patient's safety, FFP must be of the highest quality for transfusion, just like other blood products. A total PC of ≥50 g/L and an RLC of <0.1 x 109 cells/L are required for non-filtered FFP, per the EDQM [1]. Factors – like temperature, storage conditions, blood separation methods, and holding time – which varies from unit to unit and is currently restricted to 3 to 20 hours – can all affect these parameters [1, 8]. This period between the collection of a blood donation and its separation is necessary for phagocytosis of any microorganisms by the bactericidal action of leucocytes, and leucocyte degradation and inactivation.

Thus, the aim of this study was to investigate whether there is a statistical correlation between holding time and RLC, as well as holding time and PC on which no relative data is available in relation to holding time. In addition, the study sought to ascertain whether SPC monitoring maintained effective procedural control. It would be possible to further standardize whole blood processing if a correlation between holding time and the RLC and PC parameters could be found. To do this, the RLCs and PCs in a cohort of 100 units with a SHT and another 100 units with an LHT were measured and compared. The term "LHT cohort" describes units that are gathered, left overnight, and processed the next day. SHT units are gathered and processed in a single day, with a standing time of roughly three to four hours. RLC, PC, and FFP unit volume were measured for each of the two cohorts' units.

The volumes of FFP units varied between 251 mL and 306 mL, with the mean of the LHT cohort being higher by 7 mL than that of the SHT cohort. The volume of a unit may be influenced by various factors including the automated separator used to derive the plasma component and centrifugation speed when separating the whole blood components [1]. Unfortunately, no literature which relates SHT and LHT in terms of volumes was discovered.

FFP unit volumes differed by 7 ml between the two cohorts, with that of the LHT cohort being higher. A higher number of FFP units with elevated RLCs were identified in the SHT cohort, which also had a wider variation of values. From this cohort of 100 units, 3 were identified as statistical outliers, and overall, a total of 5 units exceeded the minimum acceptable RLC of $<0.1 \times 10^9$ cells/L, making the difference between cohorts due to a SHT more significant. All units from the LHT cohort had acceptable RLCs, although a single unit was identified as an outlier statistically. The mean RLC of the SHT cohort was more than double that of the LHT cohort. PCs were all found to be adequate in both cohorts, however there was a statistical difference between the mean PCs of the two cohorts.

Using a standard normal distribution curve, the probability of a unit having a Z-score exceeding ±3 is 0.27% (2 in 1000). Applied to a sample of 1000 units, this predicts approximately 2 outliers. In the

SHT cohort of 100 units, 3 outliers (3%) were observed – substantially higher than expected. By contrast, the long holding time LHT cohort also of 100 units had only 1 outlier (1%), which, while slightly above the expected rate, was three times fewer than in the SHT cohort. These findings indicate that shorter holding times may be associated with increased variability and a higher likelihood of units exceeding acceptable leucocyte limits.

The data collected showed that when comparing mean RLCs the two cohorts were found to be statistically different using the Mann Whitney test ($p = <0.001$), with the mean of the SHT cohort being larger (0.029×10^9 cells/L) than that of the LHT cohort (0.013×10^9 cells/L) by more than twice as much. The presence of OOS values most likely had some influence on the mean value since the data set was right-skewed, but the fact that more units with an elevated RLC were identified in the SHT cohort showed that the holding time did in fact have an influence on this parameter and this was consistent with the findings of the local establishment.

Various factors influencing transfusion products have been studied in the past few decades, however, there has been very little if any research specifically on the influence that holding time has on the RLC in plasma [5, 8–14]. There was a similar study carried out by van der Meer et al. [13] where this correlation between RLC and holding time was tested in whole blood and leucodepleted red cell concentrates. RLCs were measured at different holding times and were found to increase with a longer holding time prior to whole blood processing [13, 14], whereas the findings in the current study showed that the mean RLCs decreased with time, most likely due to leucocyte degradation. However, it must be considered that in the study by van der Meer et al. [13], this parameter was tested in other blood products and not FFP. Additionally, in contrast to the current study, which used non-filtered FFP, the blood products were leucodepleted before testing. Regarding PCs, the p-value from the independent samples T-test ($p = <0.001$) indicated that the means of the two cohorts were statistically different, even though no outliers were found and all PCs were above the EDQM's minimum limit (i.e., ≥50 g/L). Given that the LHT cohort's mean value was higher (62.55 g/L) than the SHT cohort's (60.52 g/L), this would suggest that a slightly higher mean PC was the outcome of a longer holding period.

Proteins in plasma products have been studied more thoroughly than RLCs, but these studies tested specific proteins, primarily coagulation factors, rather than total PCs [10, 12] In the three primary blood products (red blood cells, pooled platelet concentrates, and plasma), Lu et al. [9] tested and compared a number of parameters in units with a holding time of up to 8 hours and others with an overnight holding time (24 hours). With the exception of FVIII, which lost about 20% of its activity after an overnight hold at room temperature, there were only slight differences in the levels of the coagulation factors (FII, FVII, FV, FIX, FX, and FXI; fibrinogen; and von Willebrand factor) that were tested in frozen plasma. Thus, apart from FVIII, other proteins were still at acceptable concentrations even after a 24-hour holding time [9]. This finding correlates with the current study since the total PC was at acceptable values in units with a SHT and was still at acceptable values in units with a LHT (up to 20 hours). Although contrary to current literature evidence, the mean PC in the current study was higher for units with a LHT.

Several studies [4, 5, 10, 11] have investigated the changes in coagulation factor levels with changes in holding time. Like the previous study mentioned, most proteins and coagulation factors were found to be at acceptable levels even after a holding time of 24 hours, but like many research studies they highlight a decrease in the levels of FVIII. This decline in FVIII is now well known and may not always have clinical relevance [14]. In fact, because FVIII is known to decline over time, the EDQM views it as a highly reliable indicator of product quality. In addition, Cardigan et al. [4] tested prothrombin, fibrinogen, FVIII, protein C, protein S, and activated partial thromboplastin time. In contrast to other coagulation factors tested, the results indicated that these were marginally but significantly decreased when comparing an 8-hour to a 24-hour holding time. Most proteins, some more sensitive than others, deteriorate over time. In the present investigation, however, a longer holding time was associated with a higher mean total PC.

The SPC results showed that processes for volume and PCs were within control for both the cohorts. On the other hand, the cohort's RLC process was unable. The results further demonstrated the influence of the OOS values when recalculated with OOS excluded. In the SHT cohort, the RLCs' capability outcome improved from incapable to borderline. Because the capability outcome was still borderline, it can be inferred that even in the absence of OOS values, the RLCs of the units in the SHT cohort might not always be within process control in subsequent measurements. The wide range of values in this cohort was probably the reason why the RLC process did not become capable. The necessity of monitoring FFP units with a SHT is consolidated by SPC results for RLC. The LHT cohort immediately showed a capable outcome for all parameters, confirming that the values were consistently within process control.

LIMITATIONS

Although informative, this study had its limitations. Undoubtedly the larger the sample size, the more accurate and reliable results are in any study. Having a small sample size of 100 unit per cohort limits the accuracy of the conclusion made by this study. Nonetheless, it still provides essential data and sets a good foundation for more extensive research if required.

Another limitation of this study was related to the FFP units tested in the two cohorts. Although ideal, it would not be feasible for the same units to be used for both SHT and LHT. Hence the units of the SHT cohort were derived from whole blood units that were different from the 100 units of the LHT cohort. Using the same units for both cohorts would allow the observation of how the RLC and PC change with time in the same unit, however the holding time is defined as the time between whole blood collection and its separation into the main blood components. Thus, units with a SHT would have already been processed, and therefore, cannot be put back together and tested after an LHT. In addition, the FFP product is not very stable and testing the unit twice would require keeping the product at higher temperatures for longer than recommended since it is ideally frozen as soon as possible to maintain the levels of coagulation factors, particularly FXIII. Hence, this would likely result in lower PCs as certain labile proteins start to degrade after a few hours [1, 15].

The limited literature available on the influence of holding time on the parameters involved in this study made it challenging to compare the findings obtained. Although, these hinted towards being consistent with the findings of the local establishment. In addition, studies found in the available literature opted to investigate coagulation factors and not total PC, making it difficult to determine how the total PC results relate to these studies.

FURTHER WORK

There are endless possible studies to perform on non-filtered FFP and how holding time and other factors impact the different components of this blood product.

First off, more FFP units would be involved, which would increase the precision and validity of the data collected and the conclusions or hypotheses drawn. This is essential when attempting to continuously improve protocols and make sure that the modifications made in response to data collection will, in fact, produce the intended results.

The units can be divided into two cohorts with short and long holding times, and the holding time in hours of each unit can be estimated. This would allow graphs to be plotted to show how parameters change as holding time increases. By keeping track of the hours that passed between the time the whole blood was donated and the time the finished FFP product was obtained, this can be estimated.

Measuring individual proteins, especially coagulation factors at different holding times in addition to PC can be used to evaluate how the level of each protein is affected.

CONCLUSION

The findings of this study indicate that holding time before whole blood processing affects the RLC and PC in non-filtered FFP units; therefore, the study's goal was accomplished since a correlation was found. RLCs in FFP were found to decrease while PCs increased with an increase in the holding time

of whole blood. The SHT cohort of this study also included units with an elevated RLC, as determined by the local establishment. To lower the possibility of having units that don't meet quality standards and having to throw them out, it might be advised that the current minimum holding time of three hours be raised.

However, a qualification procedure should be established to determine the optimal range of holding time duration required to obtain FFP units with low RLC levels and adequate PCs.

Incorporating a leucoreduction step after processing FFP could also be considered to maintain low RLCs regardless of holding time. However, to increase the holding time, a thorough and solid qualification plan that includes evaluating any associated risks and subsequent mitigation measures would need to be used.

A LHT offers additional advantages beyond guaranteeing that blood product specifications are fulfilled and protecting recipients from undesirable and preventable transfusion reactions. The blood establishment's working hours would allow for greater operational flexibility if the minimum holding time were extended (Thomas, 2010). Additionally, since whole blood would not need to be processed in a few hours, it could be left for longer, freeing up time for other high-priority tasks.

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Consent

It is not applicable.

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