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Cumulative Sum Analysis for Spinal Blockade in Novices

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Abstract

Objectives: *To create CUSUM learning curves for spinal blockade in novices with less than 3 years' anaesthetic experience and to determine the minimal number of attempts it takes to achieve competency.*

Method: *During the period June 2021 to March 2022, 5 trainees accomplished a total of 308 spinal blockades. Of the 308 that were done, 226 were used for data analysis as this figure had correlating data collection forms 1 and 2. (see supplementary files) CUSUM learning curves were created using acceptable and unacceptable failures rates determined from a consultant consensus (see supplementary files), and success and failure criteria were obtained from the literature.*

Result: *60% of trainees achieved an 85% success rate (as determined by consultant consensus) with a median of 17 spinal blockades.The true failure rate (47.5%) was higher than the acceptable failure rate (15%). Hence for 60% trainees to be deemed competent with a 52.5% success rate, 17 (15-34) spinal blockades must be performed.*

Conclusion: *CUSUM learning curves are a useful replacement to logbooks and work based assessments in determining progress and competency of trainees. More work needs to be done to obtain failure rates of expert anaesthetists in this country, so we can define acceptable and unacceptable failure rates for our population of trainees at the various institutions. Setting such standards nationally would aid the move towards competency-based training.*

BACKGROUND

Cumulative sum (CUSUM), is a statistical method that looks at the outcome rather than at the process of performing procedural skills[1], and it can be used in assessing competence during the training phase, at procedures such as tracheal intubation, spinal blockade, epidural anaesthesia, central venous and arterial cannulation. In addition, learning curves constructed from a plot of CUSUM analysis for spinal blockade can be used to determine the minimum number of blockades required to reach an acceptable level of competence for clinical practice [1], since they assess time and percentage of success performing a task. [2] Furthermore, failure possibilities of the evaluation method from the standpoint of type 1 and 2 error, and the ability to be evaluated from the point of view of acceptable and unacceptable failure probability are considered. [2]

When using CUSUM charts in the practice of anaesthetics, some studies concluded that there is a high inter-individual variation when it comes to acquiring a skill in Anaesthesia [2], since variables such as the institution where the training is done, physician preference and the number of cases to which the trainee is exposed contribute to the acquisition of a skill. [2] The importance of assessing competence in a skill in anaesthesia is to address concerns regarding lack of training opportunities and to determine when a trainee is competent at performing the skill. [3] Training programs can also be enhanced by defining an optimal rate of success from the number of attempts at spinal blockade required to achieve competence. [4] In addition, it can be used as a continuous audit of quality of practice for experienced clinicians. [3]

With the ever-evolving medical field, training opportunities have declined due to a decrease in working hours and the development of a clinical environment that is time pressured. [1]Currently procedural skills are evaluated using logbook summaries and work-based assessments. [1] Disadvantages of using logbooks are that there is no record of success or failure, and no identification of unsafe or poor practice. [1] Additionally, WBAs may only assess single favourably selected episodes and the assessor can be chosen by the trainee to avoid poor reports. [1]

The ACGME, American Accreditation Council for Postgraduate Medical Education, requires that graduating trainees perform a minimum of 50 spinal techniques for surgical procedures. [1] Several studies were found in the literature to assess the number of spinal blockades performed before achieving competence, and methods by which the acceptable and unacceptable failure rates were determined.

In one study, Konrad et al [4], investigated the minimal number of cases required to achieve minimal rates of failure in regional and other anaesthetic procedures. He found that to reach a success rate of 90%, 71 attempts were required with no clear effect on confidence interval. Furthermore, most of the learning curves demonstrated a continuous improvement with some increase of the confidence interval after 90 cases for spinal anaesthesia. His study comprised

11 first year residents, supervised by a senior staff member, with patients in the lateral decubitus position and midline approach. Success (rated 1) was defined as adequate technical performance where the procedure was completed without any physical help from staff and only small doses of IV analgesics and/or sedatives were allowed with patient breathing spontaneously. A maximum of 3 attempts or elapsed time of 10 minutes were allowed. It was rated zero when physical assistance by a staff member was required. However, CUSUM analysis was not used as this would have required inclusion of Anaesthesiology staff for comparison.

In another study by Oscar David Aguirre et al [2], which evaluated CUSUM learning curves in basic Anaesthesia procedures, the conclusion was made that an expected 85% proficiency was reached after performing 35 spinal anaesthesia procedures. 4 trainees with an overall 251 spinal Anaesthesia procedures were assessed. The spinal block was done in the lateral decubitus position also, and the success criteria included: less than 10 minutes from initial puncture to needle removal, adequate depth of anaesthesia only requiring conscious sedation, no physical assistance from instructor (verbal allowed) and 3 or less attempts. In this study, the technique was first reviewed verbally and then one of the principal investigators guided the student through the procedure in real patients before the trainee was allowed to perform the spinal.

Also conducting similar research in 2002, was Oliveira Filho et al. [5] Over a period of 2 years, data on 668 spinals done by 11 first year residents were collected with no specification of position the block but done under the instructors' supervision, and remarks about the trainees' techniques were allowed. However, the difference in this study was that acceptable failure rates at the interspace first chosen for spinal was calculated by control samples of 459 spinals done by 22 staff anaesthesiologists over a period of 9 months. The success criteria included the correct identification of space at interspace first chosen followed by adequate surgical Anaesthesia which was defined as no need for opioid or GA supplementation during the surgery, and failure was when the instructors took over after failed identification of subarachnoid space at first interspace chosen or at any time if judged appropriate for patients' comfort or safety. With these differences, 7 residents crossed the 15% acceptable failure rate after 36 +/- 20.16 procedures, while each did a mean of 62.45 +/- 21.38 procedures.

Finally, Kestin et al[3], demonstrated that2 of 8 residents (25%) attained the 10% acceptable failure rate for spinal anaesthesia after 39 to 67 blocks. Success was defined as successful surgical anaesthesia after location of the subarachnoid space via the interspace first chosen. Acceptable failure rates were obtained from a consensus from consultant anaesthetists about acceptable and unacceptable failure rates for the procedure.

Therefore, success criteria determined from the studies above to investigate how many spinal blockades it takes to achieve competency can be described as follows; time from initial puncture with spinal needle until removal of no more than 10 minutes [2], 3 or less attempts at same interspace [5], no physical assistance [2], adequate depth of spinal blockade and no opioid, hypnotic or GA allowed but only midazolam for anxiolysis. [2,5]

In conclusion, although CUSUM is a valuable tool in assessing competence at spinal blockades which may be required for structured training and continuing medical education[3],its most challenging aspect in training is determining acceptable and unacceptable failure rates. Currently in this country, there are no studies from any of the institutions using CUSUM to assess performance and define competence. Further work in this area should focus on assessing the failure rates of expert anaesthesiologists so informed decisions can be made about the acceptable and unacceptable trainee failure rates. [1] Setting such standards nationally would aid the move towards competency-based training. [1] Methods to adjust CUSUM scores for predictably difficult procedures can be investigated and validation studies performed. [1] In looking to the future, as more CUSUSM data regarding spinal anaesthesia is collected nationally, appropriate success and failure rates will become defined for different groups by this performance data.

METHOD

This is a prospective observational study that aims to create CUSUM learning curves in spinal blockade for novice residents with less than 3 years of anaesthetic experience at the Eric Williams Medical Sciences Complex (EWMSC) during the period June 2021 to March 2022. From the CUSUM curves, the minimum number of attempts required to achieve competency can be determined. The hypothesis is that there is no difference in the number of attempts required to achieve competency in spinal blockade, from that predetermined by a group of consultants and that obtained from novices in the study. That is, the true failure rate is not different from the acceptable failure rate. [1,3]

To begin, CUSUM analysis is a statistical technique to distinguish deviations from an acceptable failure rate[3], and the following must be defined when plotting CUSUM charts; standard error type 1 and 2, percentage of acceptable (p0) and unacceptable (p1) failure rates for the procedure in accordance with the usually accepted quality standard in the area, decision limits h0 and h1, and s.[1,3] In addition, a pre-set success and failure criteria is established for the procedure being assessed as a binary variable. [5] With each successive failure or success at the procedure, starting at zero, positive or negative increments are added to a cumulative score, the CUSUM, which increases with failure and decreases with success. [3] Therefore, success is indicated by a declining trend and failure by an increasing trend. [3]

When the CUSUM declines below the lower boundary limit (LBL) h0, then the true failure rate is not statistically different from the acceptable rate (the null hypothesis) with the risk of type 2 error equal to beta; if the CUSUM exceeds

the upper boundary limit (UBL), h1, then the true failure rate is statistically significantly higher than the acceptable rate, with a risk of type 1 error equal to alpha; if the CUSUM stays between the 2 boundaries, then observations must be continued. [3,5]Formulas found in an article from the British Journal of Anaesthesia, "A statistical approach to measuring the competence of anaesthetic trainees at practical procedures" by Kestin et al[3], were used to calculate the values to be used to plot the CUSUM graph. The alpha and beta errors were chosen to be 0.1.[5] The formulas are highlighted below.

Alpha 0.1, beta 0.1

a = ln [1-beta/alpha] b = ln [1-alpha/beta]

P = ln (p1/p0) Q = ln [1-p1/1-p0]

h 0 = -b/P+Q

h 1 = a/P+Q

s = Q/ P+Q

During the period June 2021 to March 2022, 5 trainees accomplished a total of 308 spinal blockades. Of the 308 that were done, 226 were used for data analysis as this figure had correlating data collection forms 1 and 2.The other 5 trainees were excluded from the study as the number of spinals done were too little to be statistically significant due to training restrictions because of COVID 19.

Prior to starting data collection, suitable acceptable and unacceptable failure rates for spinal blockade when performed by a trainee of less than 3 years anaesthetic experience, were chosen by consultant anaesthetists via a consultant online survey formulated on google docs. [3]P1, the acceptable failure rate, was determined by calculating the median from the responses given by the consultants to the question, "if a trainee of less than 3 years anaesthetic experience attempts 20 spinals, how many failed attempts is acceptable to be deemed competent?" P0, the unacceptable failure rate, was calculated in a similar manner using the question, "if a trainee of less than 3 years anaesthetic experience attempts 20 spinals, how many failed attempts is unacceptable?" P1 and P0 values were then used to calculate P and Q, h0 the lower boundary limit and h1 the upper boundary limit, and s, sigma. [3]

At the start of the study, 10 trainees with the least amount of anaesthetic training but with less than 3 years anaesthetic experience, were selected from the EWMSC anaesthetic department. They were given a demographic information sheet to complete. Information gained from this included educational tools exposed to and number of spinals done before the study. [2] Also the number of years of anaesthetic experience prior to the research was accumulated. [2] The trainees were briefed via a virtual meeting, on how they will proceed to complete data 1 collection sheet. The data collection sheet was easily accessible via a link available from google docs on a group chat formulated to interact with the trainees. Each trainee was expected to perform 50-75 spinal blocks at the EWMSC and Mt Hope Women's Hospital over a period of 6-12 months. These spinal blocks were to be supervised by consultant or registrar on the list.

All subspecialties beside paediatrics and cardiac were targeted and trainees did the blocks in a consecutive manner. There was no delineation between levels of difficulty of spinals and exemption from performing such.[4]The spinal blockade procedure was not explained to the trainees prior to the study. They were expected to perform spinal blockade as they were already doing. Hyperbaric bupivacaine was used for all spinals and adjuncts were optional. The size, length and type of spinal needle used was optional based on availability at the institution. These ranged from 22GA -25GASprotte and Quincke spinal needles. Also, they performed the blocks with the patients positioned sitting or lateral depending on the nature of the clinical condition and the preference of the trainee, for ease of conducting the procedure. Confirmation that the subarachnoid space was reached was by observing the flow of CSF. [2]

Each trainee was given a number as a code, from 01 to 10, as a means of maintaining confidentiality with their data collected. This code and the spinal attempt number were to be communicated to the observer, whom they were aware would be filling out a data collection form 2 with other information they were not aware of. The observers; consultants and registrars, were also given an explanation of the study and the expectations to complete data form 2, via a virtual meeting that was done separately to the trainee meeting. Any ambiguities concerning the study and the data collection forms were cleared in these meetings and also later on in the group chats. Informed consent in writing was obtained from the trainees and observers for participation in the research. The patients were not given informed consent as the study was conducted in an academic organisation under direct supervision of all procedures by a more senior anaesthetist.

Both data collection forms were available via separate links on separate messaging groups constructed by the PI, and they were submitted to the PI's personal google account . The data collected was entered into a Microsoft excel sheet for each trainee and kept only in the PIs private possession. The CUSUM charts for each trainee were prepared using Microsoft word X Y scatter chart.

Both trainees and observers were blinded to a set of defined success and failure criteria, only known to the PI. The success and failure criteria were used to formulate the questions in both data collection form 1 and 2. Success was defined as: time from initial puncture with spinal needle until removal of no more than 5 minutes, 3 or less attempts at the same interspace (where an attempt equals removal of stylet for flow of CSF)[2],adequate depth of spinal blockade [5,8] (using any modality but not bromage) being at T10 for lower limb and pelvic surgery, and T4 for intra-abdominal surgery, and no physical assistance from the registrar or consultant (verbal assistance was allowed). [2] Midazolam was also

allowed for anxiolysis pre or post block, once the patient kept breathing spontaneously. [4]No opioids or GA were allowed. Failure was defined as inability to identify the subarachnoid space at the first interspace chosen[5], and the consultant or registrar taking over at any time if judged appropriate for the patient's comfort or safety. [5]

Because of restrictions on staff training due to COVID-19, 5 of the 10 trainees were selected for data analysis. The other 5 were excluded as the number of spinal blockades completed were insufficient to be used in the study to be of any statistical significance. For each of the 5 trainees selected, the number of attempts were taken as those that had completed forms 1 and 2 for each attempt. For each attempt that was used, it was labelled success or failure based on the responses to the questions from the data collection sheets and the pre-set success and failure criteria.

Separate CUSUM graphs were plotted for each trainee. The CUSUM axis starts at zero, and with each success the graph decrements cumulatively by s and with each failure the graph increments cumulatively by (1-s). [3,5] The CUSUM graphs were plotted with CUSUM value on the y axis and the number of attempts on the x axis[3],and used to determine how many spinal attempts it takes to achieve competence, which should be when the line steadily falls below the h0, the lower boundary limit. [5]When it falls below h0 from above, then the null hypothesis holds that the true failure rate is not statistically different from the acceptable rate, with the risk of type 2 error equal to beta. [5] If the line remains between h0 and h1 then the results are inconclusive and no statistical inference can be made indicating that the trainee will be required to perform more spinal blocks until the line falls below h0 or rises above h1.[5] If the line rises above h1 and remains above, then the true failure rate is statistically significantly higher than the acceptable rate (the alternative hypothesis) with a risk of type 1 error equal to alpha. [5] This would imply that the trainee has not yet achieved competence at the block.

ETHICS

The sample size (35-70) for this study was determined from the literature by comparing numerus similar studies.[1,2,3,5] Ethical approval was obtained from the UWI ethics committee prior to conduction of the research after the study method was peer reviewed. Due to covid regulations, meetings with observers and trainees were done separately and virtually. In addition, data collection forms were completed online via google docs links and the forms were stored on the private investigator's (PI) personal google account. Anonymity of trainees were maintained by being assigned a number (0-10) which was used on the forms instead of their names and they were reassured that the data collected would in no way influence their appraisals at the institution, but it was solely for the purposes of the study. The analysis of trainee data was also anonymous to ensure compliance. [4] Informed verbal and written consent was obtained from both observers and trainees. Observers and trainees were blinded from knowledge of the success and failure criteria, which was only known to the private investigator.

Furthermore, the patients were protected from any harm, by the observer taking over at any time if felt appropriate as part of the failure criteria. The patients only had the spinal blockade done on them if their surgical procedure warranted it and after informed verbal consent as is usually done in the practice of anaesthesiology.

Lastly, the trainees were required to fill out forms for all spinals done consecutively whether or not success at the attempt was accomplished. In like manner the observer was expected to complete the corresponding data form 2.

The results were used to plot the CUSUM curves for each trainee from which the minimal number of spinals required to achieve competency was determined, and this can assist in the allocation of trainees during their learning process to areas where spinal blockades are in high demand.

NUMBER OF ATTEMPTS TO ACHIEVE COMPETENCE AT SPINAL BLOCKADE

Results

During the period June 2021 to March 2022, 5 trainees accomplished a total of 308 spinal blockades. Of the 308 that were done, 226 were used for data analysis as this figure had correlating data collection forms 1 and 2. The other 5 trainees were excluded from the study as the number of spinals done were insufficient to be statistically significant, due to training restrictions because of COVID 19.

The demographic data collected for each trainee can be demonstrated in table 1 below. [2]

Table 1. Demographic information of trainees

Demographics	Trainee 01	Trainee 03	Trainee 05	Trainee 07	Trainee 10
Handedness [2]	Right	Right	Right	Right	Right
Gender [2]	Male	Female	Female	Male	Female
Educational tools exposed to before study [2]	NYSORA	LPs in medicine	Teaching sessions, videos, textbooks, NYSORA	Officer in AICU PICU ACLS BLS ATLS, videos	MBBS Anesthesia clerkship
Number of spinals done prior to research [2]	55	50	30	30	>50
Number of years anesthetic experience	1 year 8 months	1 year 7 months	1 year 7 months	1 year 2 months	1 year 9 months

The acceptable failure rate p1, for spinal blockade as obtained from the consultant survey is 15% (3/20) and the unacceptable failure rate p0, is 40% (8/20). This was obtained by taking the median of the responses to specific questions from the survey which included:

- If a trainee of less than 3 years anesthetic experience attempts 20 spinals, how many failed attempts is acceptable to be deemed competent?
- If a trainee of less than 3 years anesthetic experience attempts 20 spinals, how many failed attempts is unacceptable?

Using the formulas mentioned in the method [3] and the results of the consultant survey, the s value was calculated to be 0.56, andh0 and h1 was calculated to be -1 and 1 respectively, as shown in table 2.

Table 2. Acceptable and unacceptable failure rates for spinal blockade, s, and boundary limits for CUSUM.

Procedure	Acceptable failure rate p1	Unacceptable failure rate p0	s	h0, h1
Spinal blockade	3/20= 15%	8/20 = 40%	0.56	-1, 1

Each attempt of the trainees was designated success or failure based on the following predefined criteria formulated from a collection of similar studies. [2,5]

Success criteria included:

- Time from initial puncture with spinal needle until removal of less than or equal to 5 minutes
- Three or less attempts at same interspace (attempt = removal of stylet for flow of CSF) [2]
- Adequate depth of spinal blockade using any modality but not bromage (to T10 for lower limb and pelvic surgery, and T4 for intra-abdominal surgery) [5,8]
- No physical assistance from registrar or consultant (verbal assistance allowed) [2]

Midazolam was allowed for anxiolysis for spinal blockade pre or post spinal blockade. [4] (no opioid, hypnotic or general anaesthetic GA was allowed)

Failure criteria included:

- Failed identification of subarachnoid space at first interspace chosen [2]
- Consultant or registrar took over spinal at any time if judged appropriate for patient's comfort or safety. [5]

Table 3 shows the number of true successes and failures for each trainee and number of attempts with CSF.

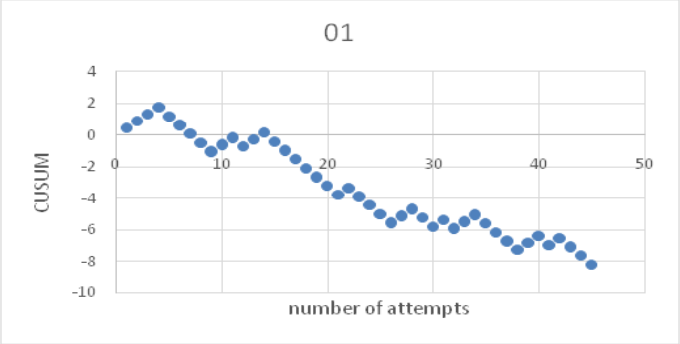
Table 3. Number of true successes and failures, and correlations with CSF, interspace and position.

	Number of successes	Number of failures	Total number of spinals analysed	Number of attempts for which trainees obtained CSF	Number of times trainee switched interspace	Number of attempts in lateral position
Trainee 01	28	17	45	37	7	2
Trainee 03	24	16	40	36	8	1
Trainee 05	18	26	44	36	12	4
Trainee 07	30	25	55	52	9	4
Trainee 10	13	29	42	35	8	0
TOTAL	113	113	226	196	44	11

These successes and failures were then plotted on CUSUM charts for each trainee. Starting at zero, s was subtracted for each success from previous value and 1-s was added for each failure from previous value. [5]

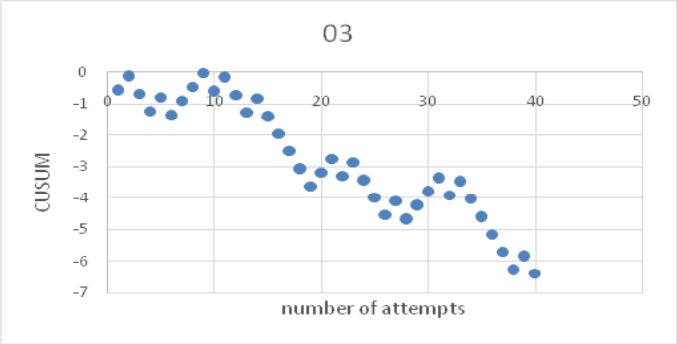
These CUSUM graphs are shown below.

Graph 1 – trainee 01



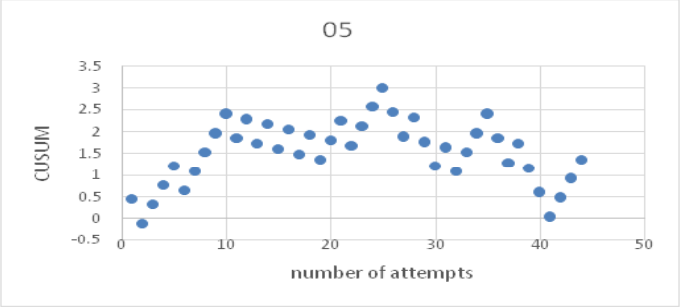
The graph 1 above shows the CUSUM plot for trainee 01. This trainee did a total of 89spinals for this study but only 45wereanalyzed. The graph crosses the upper boundary limit (UBL) from below, at attempt 3 and stays above for 3 attempts before going down again. Thereafter, it remains within the UBL and lower boundary limit (LBL) for the next 3 attempts. At attempt 9, the plot falls below the LBL from above for 1 attempt but then goes back to in between boundaries for another 7 attempts. Finally, the plot fell below the LBL from above again at attempt 17 and showed a steady decline for 3 consecutive boundary lines. Thereafter, the graph shows a steady plot horizontally. After this, it trends downwards again for 2 boundary lines after attempt 42.

Graph 2 – trainee 03



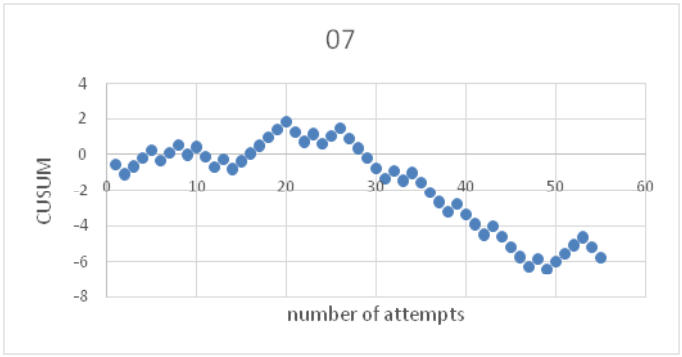
Graph 2 above shows the CUSUM plot for trainee 03. This trainee did a total of 58 spinals for this study but only 40 were analyzed. Trainee 03 crosses the LBL from above4 times at attempts 4, 6, 13 and 15 before showing a steady downward trend. After attempt 15, the CUSUM plot shows a downward trend crossing 5 boundary limits. For attempts 20-24 and 29-34 the graph is steady horizontally but still below the LBL. After attempt 34 it shows a decline again for 3 boundary limits. Of note, the UBL was never crossed.

Graph 3 – trainee 05



The graph 3 above shows the CUSUM plot for trainee 05. This trainee did a total of 49 spinals for this study but 44 were analyzed. This trainee's plot has never crossed the LBL. The graph initially stays within the UBL and LBL for the first 4 attempts, and from attempt 5, the UBL is crossed once from below and then falls between limits for one attempt. However, from attempt 7 to 39, the plot stays above the UBL but then falls in between limits for the next 4 attempts. The final attempt crosses the upper limit again from below.

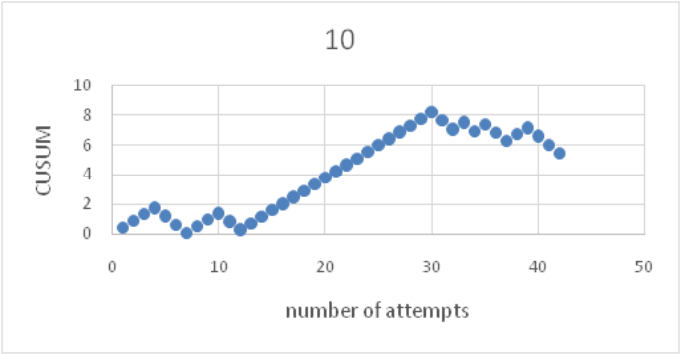
Graph 4- trainee 07



The graph 4 above shows the CUSUM plot for trainee 07. This trainee attempted 62 spinal blockades in total but 55 were used for analysis.

This trainee crosses the lower boundary at attempt 2, however, the plot remains steady between the UBL and LBL for the next 16 attempts. At attempt 19, the UBL is crossed for 3 attempts. Also, for attempts 23 and 26 he crosses the UBL again but mostly stays between boundaries from 22 to 30. At attempt 31 the LBL is crossed for the first time but only after his 34th attempt the graph shows a steady downward trend below the LBL.

Graph 5- trainee 10



The graph 5 above shows the CUSUM plot for trainee 10. This trainee attempted 50 spinals in total but 42 were used for analysis. This trainee crosses the UBL at attempt 3, remains above for 3 attempts and then stays between boundaries until attempt 10 where the UBL is crossed from below for one attempt, then again stays between boundaries for a further 3 attempts. However, from attempt 14 onwards, the graph crosses the upper boundary from below and shows a steady incline, until between attempts 31 to 42 there are a mixture of successes and failures causing the graph to show a horizontal trend, but still above UBL.

ANALYSIS OF RESULTS

5 trainees accomplished a total of 308 spinal blockades. Of the 308 that were done, 226 were used for data analysis as this figure had correlating data collection forms 1 and 2. (table 5) The expected sample size was 50-75 spinal per trainee, totaling 250- 375 spinal blockades. However, the sample size obtained in this study was 226, where each trainee had 40-55 spinals each.

60% of trainees achieved the acceptable failure rate of 15 % (3/5), and 40% (2/5) of trainees achieved a failure rate significantly greater than the unacceptable failure rate of 40%. (Table 4) From the consultant survey, the median number of attempts to achieve competence was calculated as 50, and from this study, this was shown to be 17 (15-34). (Table 6)

The null hypothesis is the true failure rate is not different from the acceptable failure rate. [3] The median true failure rate of 47.5% (table 6) was slightly higher than the unacceptable failure rate of 40%. However, it was significantly different from the acceptable failure rate of 15% and therefore, the null hypothesis is rejected.

From this study, 86.7% (196/226) of attempts had a positive CSF tap. (Table 3)Of the 196 that was positive for CSF, 113 (57.7%) was deemed as successful using the predefined success criteria. Overall, 50% of attempts were deemed successful. (Table 3)The mean time for introduction of spinal needle until removal was 1.8 minutes and the average number of attempts per spinal, whether the interspace was changed or not, was 2.2 attempts. 19.5% (44 out of 226) of attempts had a switch of interspace, and most of the spinal blockades were performed with the patients in the supine position. 11 out of 226 patients had spinal blockade in the lateral position. (Table 3)

Table 4. Outcome for 5 trainees performing spinal blockade

Procedure	Acceptable failure rate 15% No of trainees/ range of attempts to statistical significance	Unacceptable failure rate 40% No of trainees/ range of attempts to statistical significance	No statistical significance No of trainees/ range of attempts
Spinal blockade	3 (15-34)	2(3-19)	0

Table 5. Table showing number of attempts to achieve competence.

trainee	Total no of spinals in study	Total no spinals used for CUSUM	No of attempts to achieve true competence by CUSUM	No of attempts to cross upper limit initially	No. of failures or true failure rate/ failures until 40 attempts
1	89	45	17	3	17 / 16
3	58	40	15	0	16 / 16
5	49	44	Not competent	5	26 / 23
7	62	55	34	19	25 / 19
10	50	42	Not competent	3	29 / 29
TOTAL	308	226			

Table 6. Table of competence.

	Trainee 01, 03, 05, 07, 10	Percentage
Median true failures in total	16 17 25 26 29 = 25	
Median true failures up to 40 attempts	16 16 19 23 29 = 19	Median true failure rate 19/40 =47.5%
Median attempts to reach true competence	15 17 34 = 17	
Range of attempts to become competent	15-34	
Number of trainees competent after the study	3/5	60%
Number of trainees not competent after the study	2/5	40%

Analysis of CUSUM plots for each trainee

Trainee 01

Initially the trainee is incompetent for 3 attempts before downwardly crossing the UBL for 1 attempt. Thereafter it remains within the upper and lower boundary lines for the next 3 attempts. At attempt 9 the plot falls below the lower boundary line for 1 attempt but then goes back to in between for another 7 attempts, indicating a mixture of successes and failures. The trainee had to perform 9 spinal blockades before an improvement in his technique was evident. Failures were mainly due to positioning in sitting position mostly and one in lateral, language barrier in Spanish speaking patients and emergency nature of some cases. Also, some patients experienced pain and discomfort less than 30 minutes into the surgical procedure. The plot fell below the lower boundary limit again at attempt 17 and showed a steady decline for 3 consecutive boundary lines. Thereafter, the graph shows a steady plot horizontally indicating some more failures and successes, this time due to the unavailability of short needles and having to use long needles with which he was unfamiliar. Also, his documentation of block height was inappropriate for the surgical procedure. Between attempts 27 and 28, the trainee did not perform spinals for 3 months. After this, it trends downwards again for 2 boundary lines after attempt 42.

Therefore, it took this trainee 9 attempts at spinal blockade to show improvement in the technique, but it was only after 17 attempts that the 85% success rate was truly achieved. At attempt 17 his true failure rate was not statistically significantly greater than the acceptable failure rate.

This trainee is a right-handed male who used NYSORA to learn spinal blockade and did 55 spinals in the 1 year and 8 months prior to entering the study.

Although this trainee did most spinals compared to the others, the number of true failures was almost like those who did significantly fewer spinal blockades.

Trainee 03

This trainee crosses the lower boundary limit downwards 4 times at attempts 4, 6, 13 and 15 before showing a steady downward trend. This can be interpreted as the trainee initially showing improvement in the technique at attempt 4 but subsequently had a mix of failures and successes, which reflected in the plot as inconclusive performance since the trend was between the UBL and LBL for most attempts in this series. During this phase, the trainee had multiple attempts and switched the interspace before obtaining CSF. In addition, some of the blocks were patchy and patients had pain and discomfort early in the surgical procedure. After attempt 15, the CUSUM plot shows a downward trend crossing 6 boundary limits indicating competence in the procedure. For attempts 20-24 and 29-34 the graph is steady horizontally indicating a mixture of successes and failures at the procedure. During this phase, the interspace was changed, and some attempts were taken over by the observer for inability to obtain CSF or interspace. One failed attempt was with the patient in the left lateral position. Also, before the phase of attempts 29-34, the trainee was out of practice performing spinals for 4 months. After attempt 34, it shows a decline again for 3 boundary limits. Hence it took this trainee only 4 attempts to show improvement in her technique and the desired 85% success rate was reached at attempt 15. Of note, the UBL was never crossed indicating that this trainee never showed incompetence at the procedure.

This trainee is a right-handed female who had some experience performing LPs in internal medicine before joining anesthesia. She did 50 spinals in the 1 year 7 months prior to entering the study.

This trainee did less spinals in total but the length of time in anesthesia was like trainee 01. However, the number of true successes and failures were almost similar, and she achieved competence at attempt 15 compared to 17 for trainee 01.

Trainee 05

This trainee's plot has never crossed the lower boundary limit indicating she never gained competence at the procedure. The graph initially stays within the upper and lower boundary limit for the first 4 attempts where no conclusions could have been made about the performance. From attempt 5, the UBL is crossed once then falls below between limits for one attempt. From attempt 7-39, the plot stays above the UBL then falls between limits for the next 4 attempts. The final attempt crosses the UBL again from below. The trend in this trainee's plot can be explained by a gross inability to easily identify the spinal space, with multiple attempts at the same interspace and frequent switching to another interspace. This resulted in a significant number of attempts where the observer had to take over. This trainee had 2 separate months free from performing spinal blocks but with no significant connection to successes and failures. The plot shows that this trainee is incompetent at spinal blockade. A further trend in the graph is needed to make a solid conclusion.

This trainee is a right handed female who learnt spinal blockade by different mechanisms such as teaching sessions, videos, textbooks and NYSORA. She did 30 spinals in the 1 year and 7 months in anaesthesia prior to entering the study.

Trainee 07

This trainee crosses the lower boundary at attempt 2 however the plot remains steady between the UBL and LBL in the indeterminate region for the next 16 attempts. At attempt 19 the UBL is crossed upwards for 3 attempts, indicating incompetence for that phase. These failures can be explained by the multiple attempts at an interspace, changing of interspace and documentation of inappropriate block height for a particular surgical procedure. This trainee only had a one-month free period from doing spinals, after which he had some failures and then mostly successes with

few failures in between. For attempt 23 and 26 he crosses the UBL again and mostly stays between boundaries from 22 to 30. At attempt 31, the LBL is crossed for the first time from above, but only after 34 attempts the graph shows a steady downward trend depicting competence at the blockade. It took this trainee only 2 attempts to show improvement in technique but a success rate of 85% was obtained after 34 attempts at spinal blockade.

This trainee is a right-handed male who did 30 spinals prior to the study. He had 1 year and 2 months anesthetic experience prior to the study.

Trainee 10

This trainee crosses the UBL at attempt 3, remains above for 3 attempts and then stays between boundaries until attempt 10 where the UBL is crossed from below for one attempt, then again stays between boundaries for a further 3 attempts. At this phase, the trainee's performance is mostly inconclusive. However, from attempt 14 onwards, the graph crosses the upper boundary from below and shows a steady incline, depicting mostly failures at spinal blockade which were mostly accounted for due to using bromage to test adequacy of block or obtaining an inappropriate level of sensory block for the surgical procedure. This phase was also following a 3-month period of not performing spinal blockades frequently. Between attempts 31 to 42, there are a mixture of successes and failures causing the graph to show a horizontal trend, but still above UBL. Other reasons for failures during this phase included switching interspace, converting to GA or supplementing with hypnotic or analgesia, inability to obtain interspace in obese patients with long spinal needle and unable to get interspace in uncooperative patients. This trainee shows incompetence at spinal blockade, never actually crossing the LBL from above. Although the graph starts to show a downward trend, it is not steady, and several attempts will be needed before a solid conclusion can be made.

This trainee is a right-handed female who did more than 50 spinals prior to the study. She had 1 year and 9 months experience in anesthesia prior to entering the study.

DEFINING A GOOD QUALITY OR SUCCESSFUL SPINAL ANAESTHETIC

Results

This part of the study is a narrative review of what comprises or influences a successful or good quality spinal blockade for surgical procedures.

This study included mostly obstetrics, gynecology, and orthopedic patients. The majority 86.3% were females, 64.2% ASA2, 49.6% of urgent nature and 33.2% normal BMI. (Table 7) Of note, overweight and obese patients were almost of similar quantity; 32.7% and 27.9% respectively. (Table 7) In summary, our population of patients were ASA2 caesarean sections (C-sections) of urgent nature and a wide range of BMIs.

Table 7. Table showing patient demographics.

	Frequency	Percent
GENDER		
Male	31	13.7%
Female	195	86.3%
Total	226	100
BMI		
<19	14	6.2%
19-25	75	33.2%
25-30	74	32.7%
>30	63	27.9%
Total	226	100
ASA		
ASA1	66	29.2%
ASA2	145	64.2%
ASA3	15	6.6%
Total	226	100
TYPE		
Elective	71	31.4%
Urgent	112	49.6%
Emergency	43	19.0%
Total	226	100

Since our population comprised mostly C-sections, the focus of this discussion weighs heavily upon such. Our 5 trainees used a range of 1.9-2.7mls of 0.5% heavy bupivacaine for spinal blockade for C- sections. The average dose used was 2.5mls. For this mean dose of 2.5mls, block heights were documented as T2, T3, T4, T6, T8, T10 with varying modalities, and sometimes bromage only. Of the 131 cesarean sections that were done by the trainees, they obtained CSF for 112 patients (Table 8), and of the 112 patients for which CSF was obtained, 8 patients needed rescue analgesia which consisted of opioids, ketamine, midazolam, or conversion to a GA. (Table 8) Therefore, 7.1% of patients for whom CSF was obtained needed rescue analgesia. These blocks were documented as complete with a sensory level of T4 to cold mostly, T4 to touch, T6 to cold and bromage. (Table 8)

Table 8. Table showing number of attempts by trainees for C-sections with CSF, and number of patients who required rescue analgesia.

Trainee	Number of attempts for caesarean sections with CSF	Number of patients needing rescue analgesia and level of block and modality
Trainee 01	21	1 T4 cold
Trainee 03	20	2 T4 touch, T4 cold
Trainee 05	24	2 T4 bromage, T4 bromage
Trainee 07	27	1 T4 cold
Trainee 10	20	2 T6 cold, bromage
TOTAL	112	8

ANALYSIS OF RESULTS

At our institution, the dose of heavy bupivacaine used is adjusted to the height of the patient and a lower dose is used for C-sections. From the results, the range of doses of heavy bupivacaine for C-sections was 1.9-2.7mls. In addition, the most common modality and level used to test the block is T4 to cold, although it varies depending on individual physicians, hence for our success criteria, a block height of T4 to any modality besides bromage was used.

Although our trainees performed spinal blockade in an average of 1.8 minutes with a mean of 2.2 attempts, and 44 out of 226 attempts had a switch of interspace, the main factors influencing a true failure rate of 47.5% were the level of block, bromageas the only method to test the block and the need for rescue analgesia. Some trainees had a complete block with documented levels to cold at T6 but since our success criteria required the block to reach T4, these attempts were deemed as a failure. According to a study by Russell [8], if touch is found to be 2 dermatomes lower than cold, then a block to T4 with cold should mean that, to touch the level is at T6.

However, other studies are conflicting suggesting that segmental differences between the level of block assessed by pinprick and touch have differences ranging from 0 to 10 segments in some women. [8] Some studies used sensory loss to cold at T5 [9], cold at T4 [10], pinprick and cold at T6 [8], or touch at T6. [8] Whether a change in our success criteria to achieve a block at T6 to touch, cold or pinprick, would make an improvement in the true failure rate of our trainees is an interesting component to be investigated.

It is common practice at our institution and clinical trials have confirmed that patient height is an important factor in determining final block height. [10] While a lower dose is associated with fewer adverse effects, it is at the cost of a lower anesthetic efficacy, which could compromise adequacy of anesthesia and require supplementary analgesia with possible neonatal consequences and may require conversion to GA. [10] In a study by Nofal et al [10], whether the minimum effective volume of bupivacaine in spinal anesthesia for elective C- section differ with height was investigated. The upper level of sensory block was loss of cold sensation mid clavicular line to T4 and every patient was assessed for hemodynamics, degree of sensory and motor blocks. They found that the volumes of 0.5% heavy bupivacaine with fentanyl which produced effective spinal block in 90% of parturients undergoing C- section were2.62, 2.76, 2.8mls in the following heights 150-159cm, 160-169cm and 170-179cm respectively.

In contrast, a study by Bialowolska et al [9], debated the optimal dose of LA for C-section, by comparing a fixed dose of 12.5mg with a height adjusted conventional dose of 9-13mg, both with fentanyl. In the fixed dose group, only one patient required IV analgesics despite a block to more than or equal to T5, whereas in the height adjusted dose group 2 patients required similarly. Their aim was to achieve a sensory block to greater than or equal to T5 within 10minutes with no need for supplementary analgesia. They concluded that a fixed dose regimen of 12.5mg was equally effective and did not increase the risk of spinal block related complications.

Despite the dose of LA and height of patient being potential factors that affect height of a block, the other issue is the modality for testing sensory loss and the level to which this must be obtained for each modality, as was highlighted earlier. In a study by Kocarev et al [11], it was shown that the coefficient of variation was highest with ethyl chloride (24.08%) and lowest with cotton wool (10.5%). Whereas a study by Russell [8] tried to address this issue by comparing

cold, pinprick and touch for assessing level of spinal block at C-section, and the results suggested that for clinical purposes, there is no difference in outcomes whether neurotip touch or ethyl chloride spray touch sensation is used. They used diamorphine 100mcg/ml mixed with heavy bupivacaine 0.5% and no patient felt any pain or discomfort provided that the block to both modalities included T6 or above. In Russell's study, data indicated a median group difference, but not individual, of 2 segments between the level of block to touch and that to sharp, pinprick or cold. Of note, is that many published studies which used a level of block to pinprick to T4 to indicate adequate anesthesia for C-section was unreliable as intraoperative supplements ranged from 0-95%. [8]

In our study the 8 out of 112 C-sections that needed rescue analgesia had blocks to T4 to touch and cold, T 6 to cold and a bromage of IV. Hence, there is no clear reason with respect to modality and level, why these patients needed to be supplemented. While most studies suggest that block to T5 to touch is required before surgical incision for C- section, the continuing issue is trying to predict the level of touch from cold or pinprick. [8] Rocco et al [8] acknowledged that knowing the level of one sensory modality did not allow prediction of another. Russel also confirmed these findings. Also, there is an unresolved debate as to the dermatomal level and density of differential block needed to achieve adequate patient comfort as the results from various studies are conflicting. [11] Additional factors that affect this include operative technique and patient anxiety, which are not included in such studies. [11] Instead robust outcome measures such as the need for rescue GA or IV supplementation and less robust VAS have been reported. [11]

DISCUSSION

CSA is a useful tool to monitor performance and quality control in professionals trained in a particular skill and it can also be used to monitor the effects of a prolonged period away from work and the impact of new equipment on performance and therefore advice on procurement of medical supplies.[6]Moreover, it is a more sensitive tool in assessing skills compared to logbooks and work-based assessments. Ensuring competence in procedural skills in anesthesia is required to address concerns regarding the lack of training opportunities and to show that the delivered training is effective [3], and this in turn can be used to inform and evaluate training programs and guide rotation of trainees based on their educational requirements. [5]

Currently, the ACGME requires graduating residents to be able to perform a minimum of 50 spinals and 50 epidurals for surgical procedures. [1] Also, Kopacz et al [7], concluded from their study that 20-25 procedures are necessary before improvement in spinal technique but if a 90% success rate is desired, 45 attempts at spinal anesthesia may be required. Regardless of the several studies done, an accurate estimate of the actual number needed is challenging to provide since there are varying definitions for success and failure criteria, and acceptable and unacceptable failure rates, and the sample sizes are small. [1] Also, the feasibility of acceptable failure rates depends on teaching methods which may vary by institution, consultant to trainee ratio, time available for training and the number of procedures to which trainees are exposed. [5]

Furthermore, to construct a CUSUM graph, acceptable and unacceptable failure rates, and type 1 and 2 (false positive and negative errors) are needed. When alpha and beta are equal then the boundary limits are equal.[5] In this study, the acceptable and unacceptable failure rates were determined from a consultant survey. They were 15% and 40% respectively. Kestin and Naik [1], also used expert consensus to determine acceptable and unacceptable failure rates in their study. Oliveira Filho used rates from a control sample of trained anesthetists. [1]

In spinal anesthesia, success criteria for Kestin and Filho was similar, being adequate surgical anesthesia. [1] Kestin used less lenient acceptable (p1) and unacceptable (p0) failure ratesof 10% and 20%respectively, and only 25% was deemed competent. [1] The range of attempts to achieve competence was 39-67.[1] On the other hand, Filho used less stringent p1 and p0 rates of 15% and 30%, and 64% of trainees were deemed competent. [1]The range of attempts to competence was 13-68.[1]In another study by Oscar David Aguirre et al[2],he first reviewed the technique with the trainees (first year residents) and tighter success criteria was established, almost similar with this study, with an acceptable failure rate of 15% (85% success rate). 50% were deemed competent for approximately 35 attempts.[4] Konrad et al [4], also used similar success criteria as this study but in first year residents and time from puncture until removal of needle of less than 10 mins as opposed to less than 5 minutes in this study. To achieve a success rate of 90%, 71 attempts were required. This may have been too stringent a success rate. The difference for Aguirre and Konrad was that first-year residents were used, and time taken to perform spinal was no more than 10 minutes, compared to 5 minutes in this study with trainees having more than one year but less than 2 years anesthetic experience.

The acceptable and unacceptable rates in this study were 15% and 40 %, almost similar with Filho and Aguirre who used less stringent rates, and 60% (3/5 trainees) were deemed competent. The range of attempts to achieve competence were 15-34, slightly lower than that in Filho's study but similar with Aguirre.

While it has been recommended that acceptable failure rates be set initially at higher values to allow beginners to reach them after a small number of attempts[1],as residents achieve these initial rates, it is the expectation that the CUSUM line is recalculated at progressively more stringent failure rates until acceptable failure rates reach the desired level. [1]The acceptable failure rate in this study was less stringent. First year residents were used for the studies done by Aguirre and Konrad, and in this study, trainees had more than one

year but less than 3 years' experience in anesthesia, with most doing approximately 30-50 spinals prior to the study. Whether these attempts prior to the study were successful or not, by the success criteria defined for this study, is not known. However, the numbers would seem to suggest that the number of attempts required to achieve competence as shown in several studies, was already met by the trainees prior to the study. Nevertheless, these attempts may not have been performed continuously, as trainees would infrequently be rostered before the study on lists where patients consented for spinals for their surgical procedures. Also, the true failure rate of the trainees' attempts prior to the study is unknown.

Furthermore, the probabilities of type 1 and 2 errors and the difference between the p1 and p0 are major determinants of an adequate sample size and the angle of the upward inclination of the CUSUM curve at each failure as determined by 1-s. [5] It has been recommended that for a given size of alpha and beta, the difference between p1 and p0 should be adjusted to keep the angle of ascent of the CUSUM line no more than 60 degrees.[5]In Filho's study, alpha and beta were set to 0.1, and unacceptable failure rates were set by doubling p1, so the upward slopes of the curves were kept at approximately 45 degrees and the average sample size was less than 30 procedures. [5] However, this was not done for this study, but from the consultant survey, the acceptable failure rate was 15% and the unacceptable failure rate was 40%, more than double the p1.

Currently, there is no nationally agreed definitions for success or failure at any given procedure, and where the acceptable and unacceptable boundaries should be set, or to what degree alpha and beta errors should be tolerated. [1] Those in the literature also vary greatly. The number of competent doctors can increase dramatically simply by altering the boundaries which are influenced by p1, p0, alpha and beta errors.[1] Tight boundaries are important for quality control and assessing trained individuals. However, for novices, to allow for their learning curve, it should be wider.[1]

In addition, the accepted meaning of CUSUM defined competency in the literature is crossing h0 line from above or crossing any 2 consecutive lines from above. [1] If the p0 was less, then the number of attempts to cross from above would have been more.

The problem with the later, is that it demands a significantly larger number of successes than the former, as the distance to travel down is greater. This means that novices who had several initial failures (which is to be expected when learning a new skill) will potentially end up at a great disadvantage when trying to prove their competence. [1]This can be demonstrated between trainee 01 and 03. Trainee 01 crossed the UBL and trainee 03 did not. Hence, trainee 01 needed 2 extra successful attempts to achieve competence compared with trainee 03.Trainee 03 never crosses the UBL and achieves competency quickly at only 15 attempts compared who all crossed the UBL. Trainee05 and 10 who never crossed the LBL and stays above the UBL mostly, although achieving some successes in between, needs a significant number of successes now to cross 2 boundary lines (UBL and LBL) to be deemed competent.

It is suggested that the CUSUM be reset to zero each time the UBL and LBL is crossed, and that reaching a steady state on the graph may be enough assurance to conclude that the learning curve has settled down. [1]

Lastly, CUSUM graphs can be difficult to construct and interpret. [1] The acceptable and unacceptable failure rates were determined by a consultant survey and whether the rates were too lenient or not for trainees with less than 3 years' experience is not known, since there are no local rates to compare with. The number of attempts to achieve competency in this study is lower (17) than that determined from the consultant survey (50). The true failure rate (47.5%) is higher than the acceptable failure rate (15%). Hence for 60% trainees to be deemed competent with a 52.5% success rate, 17 spinal blockades must be performed. From the consultant survey responses, 60% trainees were deemed competent with a success rate of 85% after performing a median of 17 spinal blockades. This is a big difference.

Comparing with Kestin et al [3], the acceptable failure rate of 10% was described as less lenient with less competent trainees (25%). The range of attempts to achieve this was 39-67, almost like this study if including the attempts prior to the study; 17 +/- (30-50).

Maybe the acceptable failure rate determined by the consultants was too lenient, taking into consideration that each trainee did 30-50 spinals before starting the study. This explains why a small number of attempts were needed to achieve competence.

LIMITATIONS

The trainees used in this study had less than 3 years anesthetic experience. They did attempt spinals in anesthetics prior to the study, each approximately 30-55 spinals, and some trainees did lumbar punctures in medicine before entering the anesthetic department. Whether these attempts were successful or not is not known as the trainees did not log these attempts. Also, all trainees had more than 1-year anesthetic experience, but less than 2 years. Hence, their learning curve for the procedure would have already begun and the true number of attempts to achieve competence from this study (15-40) may be underestimated for novice trainees.

In addition, the final sample size used for the analysis of results may be too small, and more attempts would be required to see a consistent downward trend for some trainees to determine the number of attempts to achieve true competence. Each trainee accomplished a range of 49-89 spinal blockades. However, only 40-55 attempts were used as these had the accompanying data form 2 completed, which was needed for data analysis. The initial sample size was 50-75 spinal blockades per trainee from the methodology, so the final sample size in this study was below the lower limit.

During the study, there was the COVID-19 pandemic. Trainees participating in the study were assigned to parallel health care facilities to treat COVID patients in the ICU. Therefore, their data collection during the study was paused for 1-2 months intervals. This had an impact on the number of successes and failures for different phases in the CUSUM plot.

Furthermore, the trainees were allowed to fill out their own forms. The forms were supposed to be completed for consecutive attempts. It could have been possible that the forms were completed for the more favorable attempts, and in extension, the trainees may have selectively reminded the observers to fill out form 2 for those attempts.

The level of sensory blockade was tested using cold, pinprick, touch and bromage by the trainees. The success criteria required it to be to T4 for intra-abdominal surgery [8], and T10 for lower limb and pelvic surgery to any modality besides bromage. These were chosen as the modality varies at our institution and the studies are inconclusive regarding this matter. This success criteria were unknown to trainees and observers. They were allowed to use the method that they were trained to use at the institution. Theoretically speaking, more successes should have been obtained as the spatial blockade obtained differs based on modality used for testing the level of block. It is recommended that using light touch is the most accurate modality as it was found to have the lowest coefficient of variation. [8]

Finally, the acceptable and unacceptable failure rates for this study were obtained from a consultant survey at the institutions where the study was conducted (EWMSC and Mt. Hope Women's Hospital). There are no established acceptable and unacceptable failure rates for trainees in the Caribbean. The median rates of 15% and 40% obtained from the survey may have been too lenient when comparing with other similar studies, as the trainees had attempted 30-55 spinals prior to the study, and they had more than one year but less than 2 years' anesthetic experience. Hence, they achieved competence at a smaller number of attempts.

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