

## The Effect of Covid-19 Phase Modifications on Venipuncture OSCEs

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Received: October 14, 2021; Published: November 26, 2021

### Abstract

**Introduction:** The primary aim of this retrospective study was to determine if there was a statistical difference in the venipuncture (VP) OSCE grades with pedagogical design variants used during three Covid-19 phases in 2020 and the effect sizes of any significant differences.

**Methods:** The design variant categories in the phases were as follows (regarding teaching method, OSCE specific video accessibility and testing method): 0 (in-class, no, in-class), 1 (on-line, yes, online video assignment), 2 (hybrid, yes, in-class). The author performed retrospective analysis of VP OSCE grades by Covid-19 Phase using ANOVA and Friedman's Test.

**Results:** Statistical differences were found between Covid-19 phases with respect to VP OSCE grades ( $p < 2.1e-16$ ). Familywise comparisons revealed significant score increases as follows: 15.5 from phase 0 to 1 and 4.7 from phase 0 to 2.

**Discussion:** ANOVA and Friedman Rank Sum Test revealed a significant difference between the VP OSCE scores between phases. Difficulties and limitations discussed with particular focus on Phase 1 and possible grade inflation.

**Conclusion:** This study supported a difference between different teaching and testing methods during Covid-19 phases for VP OSCE grades. These conclusions must be balanced with limitations. Further studies should provide prospective determination of affects or interactions especially with program GPA.

**Keywords:** Chiropractic; Venipuncture; Coronavirus; Education; Procedure; Areas of Difficulty

### Introduction

Chiropractic doctoral programs were affected by the Covid-19 pandemic of 2020 [1] due to shutdowns and a shift to online learning [2]. These changes to pedagogy happened in weeks according to the Chiro Educator's Research Forum [3]. This professor and others noted pedagogical changes which included online class development, video creation for skills, video assignments, online anatomy atlas usage and massive open online courses (MOOCs) for continuing education in concussion, recorded classes, and online tutors [4]. Personal computer (PC), tablet [4] or smartphone [5] can be used to interact with many of these technological methods. Advantage and disadvantages have been mentioned in the literature [6] with scant mention of meta-analysis level evidence with high heterogeneity [7]. Although Bajpai considered linking learning theory with the intended outcomes [8], Camargo noted that Covid-19 catalyzed a worldwide change [4]. In retrospect, institutions of education need to reassess changes to make sure pedagogical changes are congruent with intentions. Therefore, this author investigated exam results and their possible relationship to modifications made during the pandemic.

Venipuncture (VP) is taught in many chiropractic colleges to various degrees. The course related to this study was taught based on CLSI protocols [9]. Our lab included arm mandrels, fake blood and the materials to perform the procedure. VP included the use of many needle types including regular vacutainer also known as the Eclipse needle (BD Vacutainer Inc.), syringe, and butterfly (winged system). According to NBCE, chiropractors "virtually never" perform venipuncture although they refer patients for laboratory analysis [10]. Chang

noted that > 60% of states allowed chiropractors to perform venipuncture if they have training [11]. Perhaps some skill development is debatable in areas such as gynecology, proctology, and venipuncture for chiropractors. However, learning these skills may provide some familiarity with common medical procedures to allow chiropractors to help in areas where phlebotomy labs are scarce.

In many colleges, assessment of skills was often performed by objective structured clinical examinations (OSCE) [12] where a rubric was scored while the student performed procedures in a simulated clinical scenario. Search protocol did not reveal any meta-analysis or RCTs for venipuncture online verses in-person assessment. Other skills such as basic life support (BLS) have been assessed [13] with low n number studies and methodological concerns [14,15]. An RCT suggested that blended learning improved knowledge [16]. However, a systematic review by Garcia-Suarez determined that the studies were of insufficient quality to make protocols for a guideline [15]. Richmond’s group authored a meta-analysis that concluded “more robust, adequately powered RCTs are needed.” Their Forest plot for practical skills showed 2 - 3 studies with an insignificant (p > 0.42 and 0.47) effect size; heterogeneity was low (I<sup>2</sup> = 0%) [17].

This author wanted to determine if the modifications to instruction and testing affected VP OSCE grades. These grades were part of a module in a course in quarter 5 or 13 in a chiropractic doctoral program. The modifications were different based upon the phase of Covid-19 as follows related to the level of State mandates. Phase 0 was a term used for the time before Covid mandates. Although quarter 201T seemed minimally affected by Covid, this term was included with > 35 quarters to serve as a control. Phase 1 was the time when only essential businesses were open. Phase 2 was a loosening of the mandates. For example, large gatherings were not recommended, bars were closed, and restaurants were at 50% capacity. In our institution, social distancing was recommended with mask usage and frequent hand washing.

The overarching tier 1 research question is R1 “what are the best methods by medical educators to improve skill training?”. More specifically, the 2<sup>nd</sup> tier research questions are as follows: R2-A “What are necessary skills for a particular profession?”, R2-B “What are the methods known at this time?”, R2-C “What metrics are best at determining specific skill learning?”, and R2-D “What are the best methods to teach a particular skill?”. Regarding R2-D, the primary aim of this study was to: R2-D1 determine if there was any difference in VP OSCE grades between different phases of Covid-19 and related modifications to teaching and evaluation.

**Methods**

Different phases of Covid-19 required different teaching and testing methods which are detailed below and summarized in table 1.

	Phase 0	Phase 1	Phase 2
Amount of quarters	35 (2011-2020)	1	1
N	2114	43	87
Teaching Platform	In-class	Online with Videos	Hybrid with Videos
Video availability	Scant	Online	Online
Teaching Structure	Group practice	At home practice, virtual classroom reviews	Practice with Professor
Assessment	In-class OSCE	Video assignment	In-class OSCE

**Table 1:** Descriptions of the phases and teaching styles.

**Teaching and assessment methods for phase of Covid-19**

The phase 0 group was prior to Covid-19 and consisted of greater than 35 consecutive quarters. The students experienced conventional teaching methods included 42-hr lectures mainly on laboratory analysis and venipuncture steps, limited video (whatever they could find on the internet themselves), PowerPoints created by the professor (Microsoft Corp) and mainly 2 weeks of 2-hr group practice weeks 5 - 6 of 11. Around week 7, the students completed an in-class written test. The scheduling of these OSCEs were accelerated due to the looming pandemic shutdowns with the last term in the 6-term sequence. Weeks 7,8, and 9 were designated for in-class OSCEs. Week 10 was for retakes. Week 11 was final exam week.

The phase 1 group was totally online (one quarter). They learned by online videos created by the professor on regular BD vacutainer (“Eclipse” needle) which were organized by weeks into the Brightspace learning management system (LMS). Also, online virtual classrooms that emphasized the main points of the videos were performed on the even weeks to provide the students time to watch the material. Two summative online quizzes were created for the midterm and Week 6 or 7. Instead of in-class OSCEs, the students had to create a video assignment to show their skills. They could pick one of the three types. Instructions were given regarding how to access the virtual

classroom and how to submit the video assignment. Make up sessions were offered the following quarter for hands on experience with Covid-19 modifications: washing hands prior to signing in with designated partners, arm mandrel cleaning before usage, social distancing except with optional designated partner (otherwise alone), mandrel cleaning after session, and washing hands.

The phase 2 group (one quarter) learning was analogous to the Phase 1 group with the following modifications. Optional in-class sessions on the odd weeks 3, 5, and 7 were implemented with simultaneous virtual classroom. Some students had to stay home for various reasons including Covid-19 infection, 14-day self-quarantine, safety of family member who are in high-risk group (elderly, comorbidities). OSCEs were performed in-class. These activities used Covid-19 modifications.

**OSCE assessment methods**

VP OSCEs are practical exams where the student performs a scripted protocol on a scenario that develops, and the student is expected to respond appropriately. The author in this study performed the scoring by using a self-made Microsoft Access database. See figure 1 for a screen capture of the database entry form for grading. Scenarios were randomized by Microsoft Access function as follows: = Int (Rnd()\*100). Therefore, students began the OSCE not knowing their assigned scenario and discovered what their scenario was as it developed. Other features of the database included OSCE schedule, automatic population of the scenario into the script, button for introduction script to student, button for “scenario only screen” for student to see, a built-in stopwatch, auto fill button, notes section, reminders to check for scenario based modifications, reminder for remaining with that changed to red when 1 minute left, procedure rubric that can be updated and printed, and perform automatic calculation of grade and percentage.

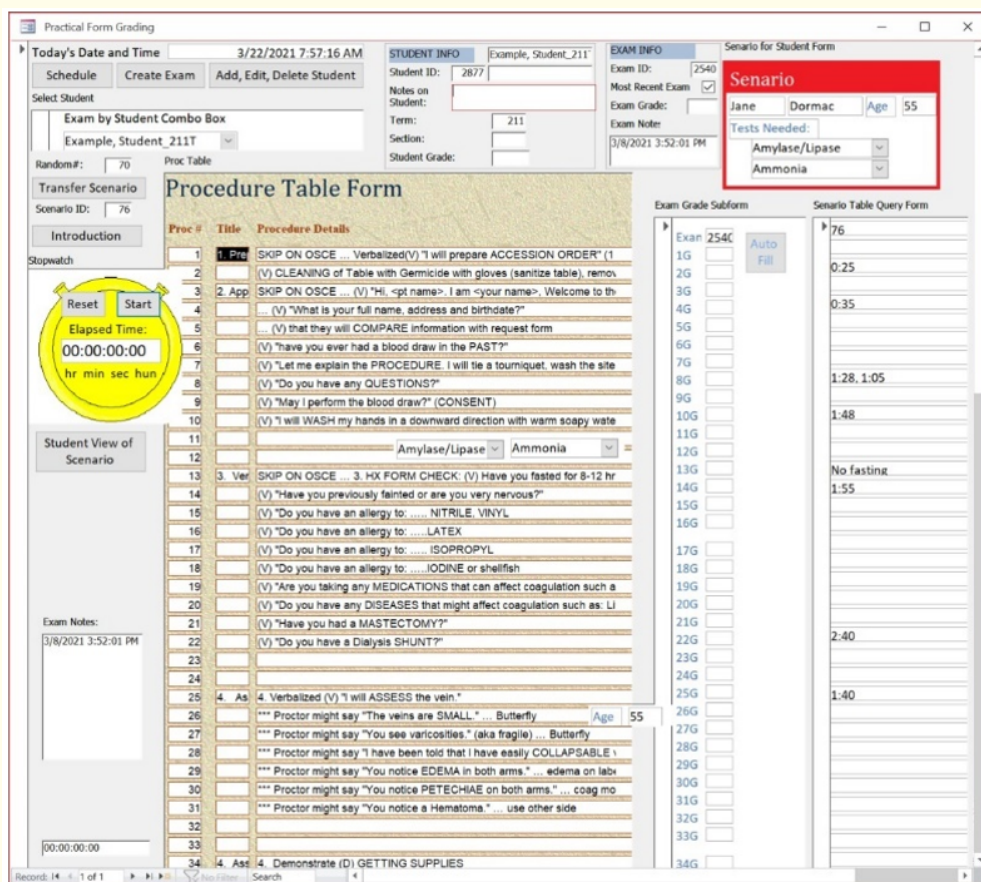


Figure 1: Microsoft access database created by author to score OSCE Rubric.

Students were graded using the rubric in table 2 which is modified from CLSI protocols [9]. Student were allotted 10 minutes. Steps with V in the parenthesis meant that the procedure was verbalized, while a D meant demonstrated. Each step was worth 2 points unless otherwise indicated like step 1. Step 17 allowed for greater than 2 point deduction due to issues with professionalism or time limit.

Proc #	Step	Proc Details
1	1. Prepare Accession Order	Verbalized(V) "I will prepare ACCESSION ORDER" (1 point/pt)
2		(V) CLEANING of Table with Germicide with gloves (sanitize table), remove gloves, wash hands
3	2. Approach and Identify the Patient; Sanitize Hands	(V) "Hi, _____. I am ____, Welcome to the clinic. Are you here for a blood draw today"
4		... (V) "What is your full name, address and birthdate?"
5		... (V) that they will COMPARE information with request form
6		(V) "have you ever had a blood draw in the PAST?"
7		(V) "Let me explain the PROCEDURE. I will tie a tourniquet, wash the site and stick the site with a needle to draw blood"
8		(V) "Do you have any QUESTIONS?"
9		(V) "May I perform the blood draw?" (CONSENT)
10		(V) "I will WASH my hands in a downward direction with warm soapy water for 2 minutes."
11		
12		
13	3. Verify Patient Diet Restrictions and Latex Sensitivity	3. HX FORM CHECK: (V) Have you fasted for 8-12 hrs before this appointment?
14		(V) "Have you previously fainted or are you very nervous?"
15		(V) "Do you have an allergy to: ..... NITRILE, VINYL
16		(V) "Do you have an allergy to: .....LATEX
17		(V) "Do you have an allergy to: ..... ISOPROPYL
18		(V) "Do you have an allergy to: .....IODINE or shellfish
19		(V) "Are you taking any MEDICATIONS that can affect coagulation such as: Heparin, Coumadin/Warfarin, Lovenox, Aspirin, Plavix?"
20		(V) "Do you have any DISEASES that might affect coagulation such as: Liver disease (Cirrhosis, Hepatitis), Hemophilia, A-Fib/Flutter
21		(V) "Have you had a MASTECTOMY?"
22		(V) "Do you have a Dialysis SHUNT?"
23		
24		
25	4. Assemble Supplies	4. Verbalized (V) "I will ASSESS the vein."
26		*** Proctor might say "The veins are SMALL." ... Butterfly
27		*** Proctor might say "You see varicosities." (aka fragile) ... Butterfly
28		*** Proctor might say "I have been told that I have easily COLLAPSABLE veins." ... Syringe
29		*** Proctor might say "You notice EDEMA in both arms." ... edema on label
30		*** Proctor might say "You notice PETECHIAE on both arms." ... coag modification (5min, comp. bandage)
31		*** Proctor might say "You notice a Hematoma." ... use other side
32		
33		
34	4. Assemble Supplies	4. Demonstrate (D) GETTING SUPPLIES
36		(D) Preparation of Reg Vacutainer (if indicated)
35		(D) Preparation of Winged system/Butterfly (if indicated)
37		(D) Preparation of Syringe: Tighten needle, Break Seal, expel air (if indicated)
38		(D) Selects correct TUBE and HUB SIZE (small tube and green hub if baby)
39		(D) Selects correct TUBE COLOR
40		(D,V) checks EXPIRATION DATES and responses properly
41	5. Position Patient	... (V) "Please sit down with arm extended." (if no other indication)
42		... (V) "Please lay down since previous Fainted or was Nervous." (ONLY if indicated)
43		... (V) "Please put out arm that does not have Mastectomy. (ONLY if indicated)

44		... (V) "Please put out arm that does not have Dialysis shunt. (ONLY if indicated)
45	6. Apply Tourniquet	6. (D) Apply TOURNIQUET; then tell patient to make FIST (1 point)
46		(D) Select venipuncture site (Landmark)
47	7. Put on gloves	7. Demonstrates (D) putting on GLOVES; choice reflects any Allergy? (1 point)
48		(D) Handle FAINTING scenario if applicable (could happen during any step)
49	8. Cleanse Venipuncture Site	8. (D) CLEANSING site spirally (Isopropyl, Chlorohexidine, Iodine OK?) in to out, air DRY
50		(D) IODINE yellow tube (if Applicable), SCOOP: Recapping of Needle system with single hand scoop technique (ONLY, if necessary)
51	9. Perform Venipuncture	9. (D) NEEDLE STICK ... A. Warn patient, retract safety, take off needle cap correctly
52		..... B. Anchor distal to site on target vein
53		..... C. Do NOT swipe over site to anchor
54		..... D. Stick.. Bevel up, 15-30 degrees, 3-4 in below tourniquet, not on thumb
55		..... E. ....One motion, Request opening of hand (no jump stick)
56		..... F. Stabilize hub and needle entire time in arm
57	10. Order of Draw	10. (D) Engagement of first tube in order: Yellow, Blue, Red, Green, Lav, Gray; tourniquet off, withdraw tube after fill
58		(D) inversion of tubes immediately after tube withdrawal: all=8, except red=6 and Blue=4
59		Waste tube on PT/PTT (Yellow counts as waste for PT/PTT if applicable)
60	11. Release the Tourniquet	11. (D) Release and removal of TOURNIQUET (should be during 10 with blood flow)
61		(D) (RE: Reg and Winded) Filling of remaining tubes in order: YBRGLGray
62	12. Place the Gauze Pad	(D) Placement of folded GAUZE over puncture site, remove needle (without tube in hub), tell patient hold time
63	13. Remove and Dispose of the Needle	(D), if using SYRINGE, remove needle with sharp container and use blood transfer device (BTD)
64		(D) activation of any SAFETY feature immediately after tubes filled and inverted and needle removed
65		(D) DISPOSAL of device (NO recap, no disconnecting needle from device except syringe) immediately
66		(D) BLOOD ... competency in obtaining blood in tubes (2 on practical) from fake arm
67	14. Bandage the Arm	(D) application of PRESSURE to site, check site to make sure it is not bleeding, if not bleeding then bandage arm
68		(D), if still BLEEDING, apply pressure for 15min, check site, apply compression bandage (fold gauze x2)
69		(V) to patient "please do NOT do any heavy LIFTING so you do not bleed out your site", release patient
70	15. Label Blood Collection Tubes and Record Time of Collection	15. Verbalized (V) remembering to LABEL tubes and date, time, initial them ... (D) putting in bag (not blue waste tube)
71		(V) Labeling tubes with "Edema" (if present)
72	16. Observe Special Handling if Required	16. (V) that one would observe SPECIAL handling (specific to test) if required (1pt)
73		
74	17. Send Blood Collection Tubes to the Proper Laboratories, Finish	17. (V) that one would SEND specimens to lab
75		Demonstrate the throwing away of materials into BIOHAZARD (NOT sharps)
76		(D) proper DISPOSAL OF GLOVES to keep blood off of sanitizing wipe container
77		Verbalize (V) Reglove, CLEANING of Table (sanitize table) with germicidal wipes, ungllove
78		(V) Washing of hands, documenting procedure in chart
79	Professionalism	(D) VP was done professionally (Manner, Attire, Organized, Adjustments)
80		(D) VP was done efficiently within 10 minute time limit

Table 2: VP OSCE rubric with steps and details.



**Statistical methods**

This was a retrospective analysis where the data was anonymized. The VP OSCE grades were grouped according to phase. Assumptions were checked and the most relevant approach to analysis was determined between ANOVA or Friedman’s test with an alpha of 0.05 with equal parsing. Planned comparison of means at the 95% CI between all group combinations using familywise error rates would be determined if test was significant. Welch F-test, not assuming equal variances, was planned if variances were unequal. The statistics platform R (R Core Team (2019). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria) was utilized for data analysis. A large Phase 0 group was used to represent normal to avoid comparison to a single cohort effect. However, since the other phases had only one representative cohort, the results may show a cohort effect for that modification.

Background literature acquisition methods included the following searches (filtered for free-full text) with results in parenthesis (initial, abstract accepted, article accepted, MA = accepted/total filtered to meta-analysis). in Pub med: Covid-19, venipuncture, online (2,0,0); Covid-19 online (4450, MA 1/21); venipuncture online (25,2,1); venipuncture web (3,0,0) online learning (12249, MA 11/68), teaching and learning (1730, MA 4/10), and online educational assessment (2343, MA 3/14). Articles from the author’s personal collection were included regarding VP demographics, protocols, and inferential statistics.

**Results**

Descriptive stats revealed means and standard deviations that were rather dissimilar as indicated in table 3. Phase 0 had an n number of 2114 which represents 35 quarters. Phase 1 had a score close to the highest and thus seemed to indicate a ceiling affect. Characteristics of a non-parametric data included disparate n numbers and variances. The standard deviation (SD) does not represent the standard error of the mean (SEM) of the sampling distribution (distribution of means). Also, it does not take into consideration family-wise comparison. Therefore, it cannot be used to determine overlap of confidence intervals. Family-wise comparisons will be handled later in this article.

Covid Phase	Restrictions and Guidance	Teaching Location	Videos Instruction by Professor	OSCE Location	Mean	SD	N
0	No restrictions, pre-Covid	In Class (group practice)	No	In-class, real time	82.9	10.9	2114
1	No contact, non-essential businesses shutdown	On-line (knowledge reviews with instructor)	Yes	On-line by video assignment	98.4	2.23	43
2	Disinfection, Social distancing, mask usage, designated partners, washing hands	In-Class (step by step with instructor)	Yes	In-class, real time	87.6	9.94	87

**Table 3:** Descriptions of the phases, teaching style and results.

Assumptions check revealed that all categories of phase had significant ( $p < 1.66e - 8$ ) non-normal distributions as per Shapiro-Wilk’s test. Although, Shapiro-Wilk’s test becomes too sensitive when N numbers are higher and thus might have considered small deviations as significant. Levene’s test was significant ( $p = 2.96e-7$ ) for heterogeneity of variance and suffered from the same difficulty with high N numbers. Phases were independent since they were different students. Phases were also independent in the sense that they did not affect each other since no one had to retake the class. Group sizes where quite different (2114, 43, 87).

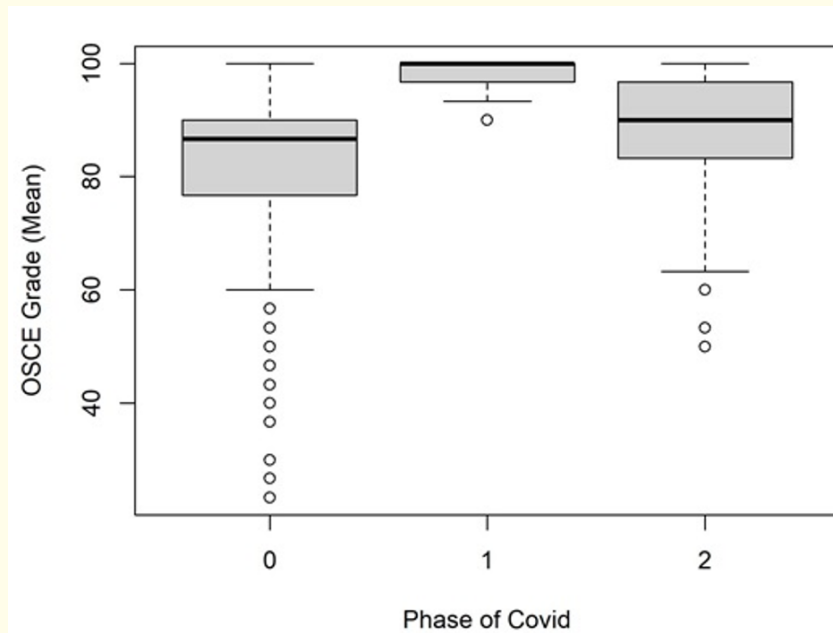
The inferential statistic ANOVA revealed p-values less than alpha and therefore significant as per table 4. For difference of means significance tests (like ANOVA) the sampling distribution should be normal (p169) [18] in the groups (p442) [18]. As per Triola, if the n numbers are above 30 then the central limit theorem can be invoked for the sampling distribution and thus it can be considered normal

[19]. However, because of the extreme differences in group sizes, variance and normality, a non-parametric test was determined to be necessary to decrease objections to the determination of significance. Friedman’s Rank Sums Test [18] was performed and revealed significance as per table 5. The null hypothesis was not supported. Therefore, there is enough evidence to support the alternate hypothesis that the different teaching and testing methods made a difference in the scores.

ANOVA	Df	Sum Sq	Mean Sq	F value	P
Phase	2	11689	5844	50.46	<2e-16
Residuals	2241	259548	116		
Friedman	Df			Chi-squared	P
	1			2244	2.2e-16

**Table 4:** Primary aim R2-D1. ANOVA and Friedman rank sum test output.

The boxplots in figure 2, illustrated the substantial differences between the sample groups. Also, left skew in noted in phase 0 and 1. Ceiling affect is represented in Phase 1 since the median is close to 100 out of 100. Outliers were not eliminated and therefore could have affected results.



**Figure 2:** Boxplots of OSCE grades by Covid-19 phase.

Figure 3 shows ANOVA related family-wise comparisons. Confidence intervals do not overlap the line of no effect and they do not overlap each other. The largest difference is between phase 0 and 1; that is, between pre-Covid and the most intense Covid lockdown phase where video assignments were assessed using the rubric. Differences from H0 represented on x-axis. Phase comparisons on y-axis. The lack of CI overlap illustrated a significant difference between groups. Analysis by estimation (effect size and confidence interval) revealed differences between groups [20]. Table 5 lists family-wise estimates of differences and confidence intervals.

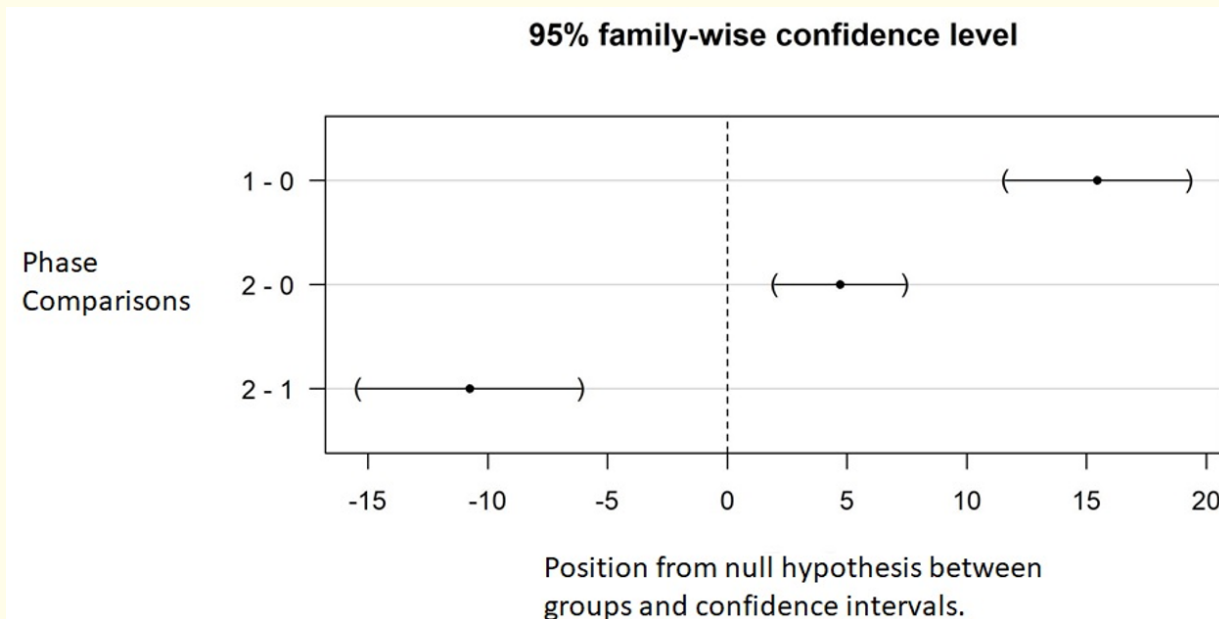


Figure 3: ANOVA ( $p < 0.001$ ) and family-wise comparisons.

Phase Comparisons	Estimate	Lower CI Limit	Upper CI Limit
1 and 0	15.5	11.6	19.3
2 and 0	4.70	1.98	7.43
2 and 1	-10.8	-15.4	-6.11

Table 5: Family-wise comparison estimates of difference with confidence intervals.

Seasonal pattern effects were explored. When the term means are plotted against the grades it produced the plot in figure 4. Seasons are related to the last number in the term: 1 = Winter, 2 = Spring, 3 = Summer, 4 = Fall. The first two numbers were the last two digits of the year. For example, the 18 of 193 represented 2019 while the 3 meant that this term is in the Summer. Phases were as follows: 0 = Terms 113 - 201, 1= Term 202, 2= Term 203. No seasonal pattern was detected since there seemed to be no correspondence. If the scores were mostly up when the last digit was 4 (in the fall) then the presence of a seasonal effect would have been noted. Again, there seemed to be no pattern.

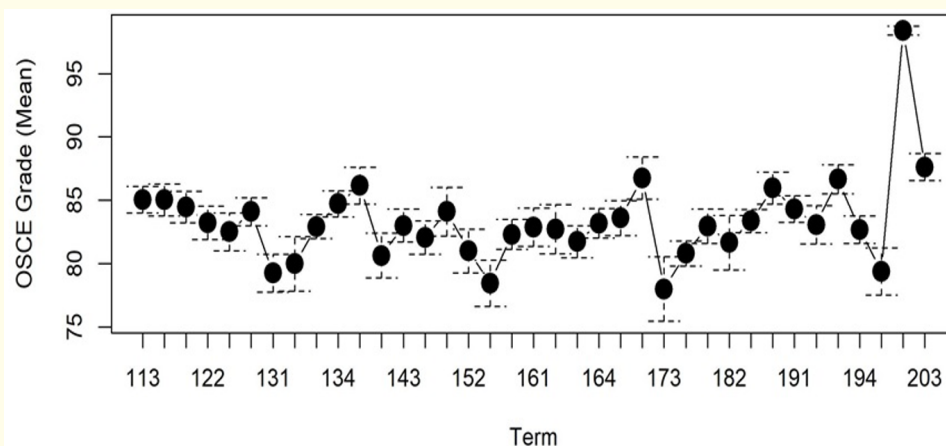


Figure 4: Seasonal pattern effects plot. VP OSCE grades by term.



### Discussion

#### Overview

This study seemed to indicate a benefit for Phase 1 methodologies including video assignment. This result required a discussion of challenges and limitations of this methodology. These differences may indicate an improvement in score yet perhaps the degree of learning is still in question. This would require further study.

#### Interpretation of results

Covid-19 phases and pedagogical changes seemed to affect VP OSCE grades to a level of statistical significance as per ANOVA and Friedman Rank Sum Test. This affect could be due to seasonal affects, cheating, distractions and other factors. Model building could be used to determine the degree of correlation. These and other difficulties will be considered individually below.

#### Difficulties

Difficulties included possible cheating, arm mandrels and materials availability, student positioning, and technical issues. Cheating could be accomplished by having a person behind the camera giving prompts or having written notes around or behind the screen. This concern was not solved during these OSCEs. Arm mandrels were not available for Phase 2 and therefore dolls, scarecrows (stuffed full body nylon suits), friends (no actual puncture), towels or pillows were used. Positional concerns involved video positioning being too far back or at the wrong angle for enhanced assessment by the examiner. Other difficulties included interruptions by parents, dogs and car noises. Technical issues during written exams were reported by another author [2]. Other authors provided resources to limit technical considerations [11].

#### Limitations of the Study

Limitations included not recording use of other VP videos on the internet by the students, possible GPA affects, retrospective analysis, ceiling affect, disparate student stress levels from Covid and assessment metrics (reliability and validity). The availability of general access online videos on the internet prior to Phase 1 might have caused the effect of videos to be decreased. The new videos created in response to Covid-19 were very specific; including the details of all three needle types (regular vacutainer, syringe and butterfly) according to the OSCE steps taught by videos. Effects were not corrected for GPA influences. Influence of stress was not reported. This study was performed by retrospective design and therefore was not optimal. Influence of stress was not able to be determined retrospectively. Ceiling affect was accentuated in Phase 1 since the students could redo recordings until they reached their goal. In addition, this study was performed in our context and would require more studies at other contexts to be more generalizable. Reliability and validity of the OSCE rubric has not been determined although it has been used by multiple professors. Morris reported that there is a lack of reliability and validity studies on assessment methods for procedural skills [21].

#### Further Study

Differential limitations and difficulties should be addressed in future research. Interactions such as GPA and stress should be considered. Another interest is to determine if any of the areas of difficulty have changed over time due to attempts to inform the students of areas of difficulty.

### Conclusion

Adaptations to Covid-19 had to be created rapidly in a skill-based venipuncture (VP) lab to provide equitable educational services. Using videos and video assessment seemed to boost exam grades massively although many other factors may be involved and an improvement in grade does not always equate to improved learning. In phase 2, the combination of video, instructor led training seemed to increase in-person VP OSCE grades significantly yet to a lesser extent. Many possibilities exist in interpreting these differences. Perhaps the student's learning improved from Phase 0 to Phase 1 due to video assignments; however, the author speculates that the scores are

hyperinflated since the students could repeat the assignment until they obtained the video submission that would probably earn the best score. It seems that Phase 2 improved compared to Phase 0 and perhaps shows either a cohort effect or improvement. Seasonal pattern changes were not evident. Limitations should be considered with the design of future research efforts. Designs should be prospective with program GPA included in the variables to rule out cohort effect. The results of the primary aim are as follows:

- Primary aim R2-D1:
- Video Assignment grades between phases 0 and 1 were exaggerated probably due to student's ability to perform the OSCE multiple times until they got the desired submission.
- Differences between Phases 0 and 2 were minimal (about 5 Grade points) without MCID established. Cohort affect needs to be ruled out.

### Conflicts of Interest

No conflicts known. No sources of funding.

### IRB Determinations

This study did not constitute human subjects research pursuant to 45 CFR 46. This study was assigned a non-human subjects assurance number, for tracking purposes only, which was N2020-9-18-M.

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**Volume 12 Issue 12 December 2021**

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