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Protocol for a randomized trial evaluating the effect of applying gamification to simulation-based endoscopy training

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Author Contributions

All authors contributed substantially to conception and the design of the protocol, all revised the manuscript critically for important intellectual content, all approved the final manuscript. All authors will have access to the final data set. MAS and SCG are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Abstract

Background: Simulation-based training provides a safe environment and effective means to enhance skills development. Simulation-based curricula have been developed for a number of procedures, including gastrointestinal endoscopy. Gamification, which is the application of game-design principles to non-game contexts, is an instructional strategy with potential to enhance learning. The application of gamification has not previously been evaluated in the context of a procedural skills simulation-based training curriculum.

Methods and analysis: Thirty-six novice endoscopists will be randomized to one of two endoscopy simulation-based training curricula: (1) the Conventional Curriculum Group, in which participants will receive 6 hours of one-on-one simulation training augmented with expert feedback and interlaced with 4 hours of small group teaching on the theory of colonoscopy; or (2) the Gamified Curriculum Group, in which participants will receive the same curriculum with integration of the following game-design elements: a leaderboard summarizing participant performance, game narrative, achievement badges, and rewards for top performance. In line with a progressive learning approach, simulation training for participants will progress from low to high complexity simulators, starting with a bench top model and then moving to the EndoVR® virtual reality simulator. Performance will be assessed at three points: pre-training, immediately post-training and 4-6 weeks after training. Assessments will take place on the simulator at all three time points and transfer of skills will be assessed during two clinical colonoscopies 4-6 weeks post-training. Mixed factorial ANOVAs will be used to determine if there is a performance difference between the two groups during simulated and clinical assessments.

Ethics and dissemination: Ethical approval was obtained at St. Michael's Hospital. Results of this trial will be submitted for presentation at academic meetings and for publication in a peer-reviewed journal.

Article summary: Strengths and limitations of this study

- The intervention in this randomized trial is a comprehensive gamified simulation-based curriculum in gastrointestinal endoscopy that includes a game narrative, performance tracking measures, and rewards. These game-design elements are grounded in educational theory.
- The primary outcome is clinical performance of live colonoscopies on real patients, which will be assessed by two blinded independent expert endoscopists using an assessment tool with strong validity evidence.
- Participants will be assessed immediately after training for skill acquisition, and 4-6 weeks after training to evaluate skill retention and transfer of skills to the clinical environment.
- There are significant human resources required for implementation with respect to tracking participants' game metrics and adjusting leaderboards.

Key Words: simulation; colonoscopy; gamification; skill acquisition

Introduction

Simulation-based training (SBT) provides a safe and effective means to enhance skills development in gastrointestinal endoscopy.[1,2] SBT is more effective when embedded within a curriculum that is grounded in educational theory.[3–6] While previous studies have demonstrated the effectiveness of comprehensive structured curricula and curricula based on a progressive learning approach[4,7], other instructional strategies may further enhance procedural skills training.

One such enhancement may lie in gamification. Gamification refers to the application of game design elements, (conceptual building blocks central to creating successful games) to traditionally non-game contexts.[8–10] The overall purpose of gamification is to "encourage behavioral change and promote desired attitudes."[11] Gamification has previously been applied in health-related settings such as health promotion and e-health.[12–14] More recently, it has been gaining traction in the medical education setting, as gamification has the potential to improve learning and learner attention, engagement, motivation and behaviour change.[8,15] In a recent randomized trial, participants were ranked on a leaderboard as they completed cardiopulmonary resuscitation (CPR) training.[16] After training, participants who were ranked on a leaderboard had significantly better technical skills acquisition on the CPR training device. Another recent trial evaluated the effect of competition on novices' ability to learn simulated laparoscopic cholecystectomy.[17] The authors found that participants who engaged in competition demonstrated fewer movements and a shorter path length, suggesting increased efficiency.

While these reports highlight the potential benefits of gamification in educational contexts, the use of leaderboards and competition represent narrow applications of gamification. To date, there are no studies that have investigated the application of a comprehensive gamified curriculum that integrates multiple game design elements for procedural learning in medicine. Additionally, no studies have reported clinical outcomes on real patients. To bridge these gaps, we aim to determine the impact of a gamified simulation-based curriculum in endoscopy on clinical performance, compared to an identical curriculum that does not incorporate game design elements.

Methods & Analysis

Study Design

This single-blinded, parallel group, randomized controlled trial (RCT) is currently being conducted at St. Michael's Hospital in Toronto, Canada. The methodology was adapted from previous studies by our group.[3,4,18] We used the SPIRIT checklist when writing our report.[19] The study design is summarized below in **Figure 1**.

Participants

Thirty-six novice endoscopists (performed < 25 previous real and/or simulated colonoscopies) will be recruited by one author (MAS). Participants will be included if they are from the general surgery or gastroenterology residency programs at the University of Toronto. Participants will be excluded if they have performed greater than 25 previous real and/or simulated colonoscopies.

Simulators

Bench Top Simulator

The bench top colonoscopy simulator is comprised of a series of vertical wooden barriers with numbered holes conforming to 27 different sequences of varying complexity. Participants use a real videocolonoscope, which provides visual output, to navigate through each sequence. This bench top endoscopy simulator helps develop general endoscopic skills and has shown good validity evidence for training novices.[20]

Virtual Reality Simulator

The EndoVR® virtual reality (VR) endoscopy simulator (CAE Healthcare, Montreal) is used for the VR training and all simulator tests. It models navigation through a colon, using a specialized endoscope that is inserted into a computer-based module with a screen showing

the colonic lumen of a virtual patient. It provides visual and haptic feedback related to the procedure. The simulator has several standardized case-based scenarios of varying complexity for colonoscopy and has robust validity evidence in the context of novices.[21,22]

Experimental Design

(1) Baseline questionnaires

Participants will complete a questionnaire to collect baseline demographic information, including age, sex, level of training, and previous endoscopic experience. Questions regarding experience with team sports and video games will also be included, as these may correlate with baseline endoscopic skil[23] (**Appendix 1**). Additionally, scales assessing the following variables will be administered: (1) competitiveness (Revised Competitiveness Index, **Appendix 2**); (2) self-efficacy (adapted General Self-Efficacy Scale, **Appendix 3**); and (3) game-type personality (Gamified User Personality Hexad, **Appendix 4**). All the included scales have good validity evidence.[24–26]

(2) Pre-test

Participants will complete a series of assessments prior to training to assess (1) their baseline knowledge of colonoscopy (knowledge test); (2) technical skills (VR simulation test); and (3) non-technical skills (VR simulation "integrated scenario" test). No feedback will be provided at any point during these assessments.

1. *Knowledge Test:* A 30-minute, 17 item multiple choice question (MCQ) test designed to assess core concepts related to colonoscopy, including indications, pathology, and theory underpinning non-technical skills (**Appendix 5**).
2. *VR Simulation Test:* A colonoscopy procedure on the VR simulator with a time limit of 30 minutes. Baseline technical proficiency will be assessed by an expert endoscopist. The procedure will be video-recorded, with identifying features hidden, to allow for a blinded assessment at a later time.[27]
3. *VR Simulation "Integrated Scenario" Test:* A test in which participants will complete a colonoscopy procedure on the VR simulator in a naturalistic setting (i.e., endoscopy suite) while interacting with a standardized nurse and standardized patient.[28] Trainees will be expected to take a brief patient history and obtain informed consent. The trainee will then carry out the procedure (EndoVR® Module 3 - Polypectomy) as described above while responding to the patient and interacting with the nurse as appropriate. As in the technical test, performance will be assessed in real time and videotaped, ensuring anonymity is preserved.

(3) Training intervention

Following the pre-tests, participants will be randomized to one of two training groups, following a 1:1 allocation distribution using an online randomization algorithm, by one author (RK). The allocation sequence will be concealed with sealed envelopes. Participants will be assigned to groups by another author (MP). Investigators will be blinded to group allocation.

1. *Conventional Curriculum (controls)*: The control group will receive a total of four, one-hour, small-group teaching sessions covering the theory of colonoscopy, including pathology, anatomy, and therapeutic technique. One session is dedicated to non-technical skills relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. In this session, participants will watch a video demonstrating ideal endoscopic non-technical skills and learn about the Endoscopic Non-Technical Skills (E-NTS) checklist which will be provided for them to use during the integrated scenario training (**Appendix 6**). This checklist was developed in accordance with evidence-based recommendations, and outlines key endoscopic non-technical skills.[29] Following each teaching session, a short MCQ test on the topics covered in that session will be administered, in keeping with the "test-enhanced learning" literature.[30] In addition to teaching sessions, the control group will be given a total of six hours of expert-assisted instruction on both the bench top simulator (1 hour) and the VR simulator (5 hours). Six modules of increasing difficulty in colonoscopy will be taught with one-on-one feedback from an expert academic endoscopist. The instructor will demonstrate techniques, answer questions and provide individualized performance feedback with a focus on non-technical skills. The last two hours of training on the VR simulator will consist of integrated scenarios, which feature a standardized patient and nurse. Following each scenario, the instructor will

debrief the trainee on their performance, using the "E-NTS Checklist" as a framework for discussing their non-technical skills.

2. *Gamified Curriculum (GC):* This group will receive the same 4 hours of small group teaching and 6-hours of hands-on simulator training. Within the context of the teaching sessions and simulator training, the gamified curriculum will incorporate the following game design elements: a game narrative; performance tracking measures; and rewards. First, a game narrative will underlie the delivery of the gamified curriculum. Participants will be assigned an avatar and will be tasked with completing a journey of the avatar around a game-board shaped like the colon (**Appendix 7**) with the goal of reaching the final destination, the terminal ileum. Second, performance tracking measures will be used to allow participants to gauge their performance over time. These measures will be summarized on a leaderboard, which will include 4 components: a non-technical skills score; a technical skills score; a cognitive skills score; and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the Modified Objective Structured Assessment of Non-Technical Skills (MOSANTS) (**Appendix 8**) and the Joint Advisory Group for Gastrointestinal Endoscopy's Direct Observation of Procedural Skills (JAG DOPS) tool (**Appendix 9**), respectively. Scoring of cognitive skills will be based on MCQ test scores from the teaching sessions. Scores will be aggregated on the leaderboard for participants training on the same days. The leaderboard will be presented to participants after they finish each hour of practice. Finally, participants will engage in a system of both short-term and long-term rewards. One short-term reward will involve badges to recognize achievements of procedural benchmarks (e.g. cecal intubation) (**Appendix 10**). Another short-term reward will be the assignment of a wearable medallion, which will be given to the participant with the highest overall ranking at the end of each hour of practice. The long-term reward will be a low-cost prize (i.e. less than $25 CAD) given to the participant with the highest overall ranking throughout practice. All three game design elements (game narrative, performance tracking measures, reward system) will be introduced to participants in the gamified curriculum group prior to training with a brief tutorial video. After watching the video, participants will receive an anonymized ID to allow for self-tracking on the leaderboard while keeping individual scores private.

   All three game design elements are consistent with recommendations from the gamification and educational literature. In line with self-determination theory, leaderboards are purported to increase users' sense of relatedness, engagement and competence through social comparison, feedback provision and documentation of achievement.[31] The rationale for achievement badges and other rewards is that they serve as visual symbol of attained goals, thus supporting participants' sense of competence and serving to foster external motivation and engagement[31,32]. Finally, game narratives are thought to enhance engagement through the integration of meaning and interaction.[9] These elements must be carefully calibrated to challenge and engage learners appropriately and to ensure maintenance of learners' intrinsic motivation.[8,15]

(4) Post-test

Participants will complete a series of assessments immediately after training (immediate post-test). These will assess: (1) knowledge acquisition; (2) technical skills acquisition; and (3) non-technical skills acquisition. They will include the same *Knowledge Test*, *VR Simulation Test*, and *VR Simulation "Integrated Scenario" Test* that participants will complete during the *Pre-test*.

(5) Delayed testing (Retention and Transfer)

Participants will complete a series of assessments 4 to 6 weeks after training to assess their retention and transfer of skills. These will assess the following: (1) knowledge retention; (2) technical skills retention; (3) non-technical skills retention; and (4) transfer of skills to the clinical environment. They will include the same *Knowledge Test*, *VR Simulation Test*, and *VR Simulation "Integrated Scenario" Test* that participants will complete during the *Pre-test* and the *Post-test*. To assess for transfer of skills to the clinical environment, participants will also complete two live colonoscopies on real patients. These procedures will be videotaped in a manner that anonymizes the identity of the participant and the patient. Procedures on

patients with a history of colonic or pelvic surgery or difficult colonoscopy will be excluded. Sedation and monitoring will be carried out according to standard practices on the endoscopy unit. An experienced attending endoscopist (completed > 500 previous colonoscopies) will provide verbal and/or hands-on assistance as necessary and take over if the participant cannot complete the procedure, or if any concerns regarding patient safety arise.

Primary outcome measure

The primary outcome measure is clinical performance during two live colonoscopies 4 to 6 weeks after training, as assessed by the JAG DOPS.[33]. Each clinical colonoscopy will be independently assessed by two experienced endoscopists who will be blinded to group assignment. One rater will be present during the procedure and the other rater will assess the participant's performance using the video-recorded procedure. Video-based assessment of endoscopic performances has been shown to have good validity evidence, compared to live assessment.[27]

Secondary outcome measures

1. Knowledge acquisition, as assessed by the MCQ Knowledge Tests
2. Technical skills acquisition during the VR Simulation Tests, as assessed by the JAG DOPS (**Appendix 9)**
3. Non-technical skills acquisition during the Integrated Scenario Test, as assessed by the Modified Objective Structured Assessment of Non-Technical Skills (M-OSANTS) for colonoscopy, which has good validity evidence for surgery and was modified for endoscopy[5] (**Appendix 8)**
4. Patient comfort during the clinical colonoscopies, as assessed by the endoscopy nurses using the Nurse-Assessed Patient Comfort Score (NAPCOMS)[34] **(Appendix 11**)
5. Participant self-efficacy after each simulated and clinical colonoscopy testing procedure, as measured by an adapted General Self-Efficacy Scale[25] (**Appendix 3**)
6. Cognitive load after each simulated and clinical colonoscopy testing procedure, as measured by the Cognitive Load Scale for Colonoscopy[35] (**Appendix 12**)
7. Participant competitiveness after each simulated and clinical colonoscopy testing procedure, measured using the Revised Competitiveness Index[24] (**Appendix 2**).

Experienced endoscopists will assess participants' technical skills and non-technical skills during the pre-training, immediate and delayed post-training simulation-based assessments.

Data Management

Data will be collected through paper forms directly from assessors. Data from the forms will be extracted and input into a database on a password-protected computer. There is no requirement for a data monitoring committee as this is not a trial addressing the efficacy of a treatment nor is patient safety at risk. Details with respect to protection of confidentiality of participant data is outlined in the participant and patient consent forms (**Appendix 13, Appendix 14)**.

Analysis Plan

Statistical analyses will be performed using SPSS version 20 (SPSS, Inc, Chicago, IL). Alpha for all statistical tests will be set at 0.05.

Baseline Questionnaire: Participant baseline variables will be characterized with descriptive statistics, using mean with standard deviation for continuous variables and number frequency for categorical variables, respectively.

Clinical Performance: Performance during the live colonoscopies will be compared between the two groups using the JAG DOPS, NAPCOMS, and MOSANTS scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (procedure 1 vs. procedure 2) analysis of variance (ANOVA) will be used. ANOVA differences significant at $P < 0.05$ will be further analyzed using Tukey honestly significant difference (HSD) post hoc tests.

Technical Performance*:* Differences in technical skills acquisition on the simulator will be determined by comparing JAG DOPS scores between groups. Specifically, a mixed factor 2 (Gamified vs. Conventional Curriculum) x 3 (pre-test, post-test, retention test) ANOVA with

Tukey's HSD post-hoc tests will be conducted.

Non-Technical Skill Performance: Differences in non-technical skills acquisition on the simulator will be determined by comparing MOSANTS scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 3 (pre-test, post-test, retention test) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Competitiveness: Baseline competitiveness, as measured by the Revised Competitiveness Index and the Gamification User Types Hexad, will be compared between groups using an independent t-test for each index.

Self-efficacy: Differences in self-efficacy between groups will be determined by comparing General Self-Efficacy Scale scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (pre-course vs. post- course) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Cognitive Load: Differences in cognitive load between groups will be determined by comparing Cognitive Load Index of Colonoscopy scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (pre-course vs. post- course) ANOVA with Tukey's HSD post-hoc tests will be conducted.

***Overall*:** A mediation analysis using a path-analytic framework will be conducted to determine the interaction of the explanatory variables on the clinical performance between the two groups.[36]

Sample size estimation

Since there are no prior studies investigating a gamified curriculum for procedural learning, we conducted the power analysis based on the effect size from a previous study that evaluated an SBT curriculum for endoscopy.[3] Based on an effect size of 1.0 (Cohen's d), an alpha of 0.05 (two-tailed), a beta of 0.20, 2 groups, and 3 measurements, a minimum of 17 participants will be required to achieve a power of greater than 0.80 using repeated measures ANOVA (between-factors). To accommodate for a potential 10% dropout and/or non-response, we will recruit a total of 36 participants.

Ethics and Dissemination

Research ethics approval was granted by the St. Michael's Hospital Research Ethics Board (17-092). Protocol version 1.0, dated March 23, 2017, was approved. If any protocol modifications are needed, they will be made after communication with the research ethics board and will be detailed in any subsequent publications. Informed consent will be obtained from endoscopist participants and patients on whom participants will perform colonoscopies by one author (MAS). No personal health data on patients will be collected. All authors will have access to trial data. We will disseminate the results of the study through peer-reviewed publication in journals and at scientific meetings. We do not plan to make participant-level data publicly available. The trial is registered at clinicaltrials.gov NCT03176251

Feasibility

To date, 21 participants have been recruited, randomized and have completed the study. Data collection is ongoing and is intended to reach completion by August 2018. Subsequent data analysis, manuscript writing and submission for publication are anticipated to reach completion by July 2019.

Conclusion

The use of SBT for procedural skills training is widespread. In the report commissioned by the Future of Medical Education in Canada Postgraduate Project, the authors conclude that "simulation… needs to be integrated more thoughtfully into postgraduate curricula."[37] We aim to respond to this call through the development of an SBT curriculum grounded in educational theory. The strengths of this study lie in its randomized design and incorporation of various game design elements into the curriculum. Additionally, the primary outcome is measured in the clinical setting by two blinded expert assessors using an assessment tool with strong

validity evidence. Finally, participants will be assessed both immediately after training for skill acquisition, and 4-6 weeks after training to evaluate skill retention and skill transfer to the clinical environment. The limitations of this study include the significant human resources required to track participants' game metrics and adjust leaderboards.

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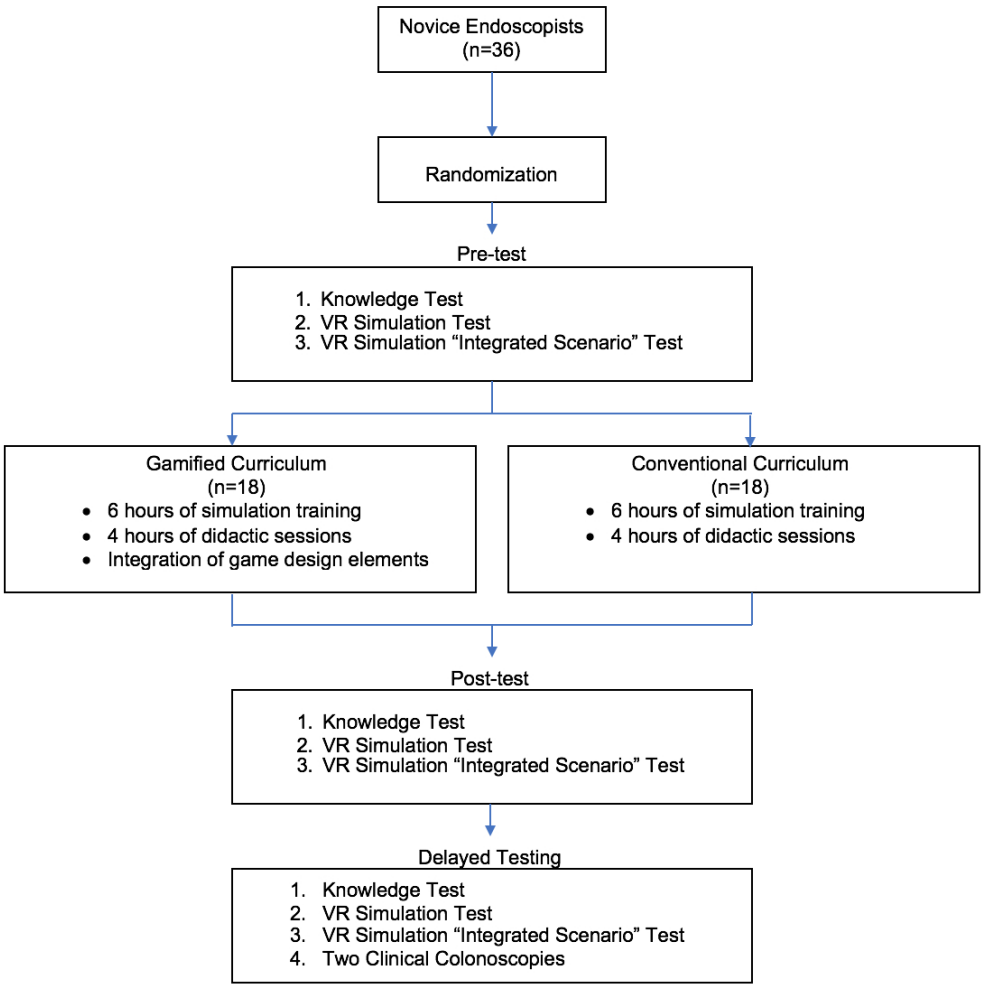
FIGURES

Figure 1: Study design.



Study design

195x198mm (144 x 144 DPI)

APPENDIX I:

BASELINE QUESTIONNAIRE

Participant ID Number: _____

1) Sex: □ Female □ Male

2) Age: _____

3) Handedness: □ Right □ Left □ Ambidextrous

4) Year of graduation from Medical School: _____

5) Programme:

□ Adult Gastroenterology
□ Pediatric Gastroenterology
□ General Surgery
□ Other (please specify: _____)

6) Level of training:

□ PGY 1
□ PGY 2
□ PGY 3
□ PGY 4
□ PGY 5
□ Other (please specify: _____)

7) Do you have previous experience in playing video games? □ Yes □ No

If yes, please specify:

(a) How many hours do you play on average per week? _____

(b) What types of games do you play? □ Sports □ Role-playing □ Real-time strategy □ Other (please describe)

8) Do you have previous experience in performing gastrointestinal endoscopy in the clinical or simulated setting? □ Yes □ No

If yes, please specify:

(c) Number of previous upper endoscopies in the ***clinical*** setting (attempted or completed): _____

(d) Number of previous upper endoscopies in the ***simulated*** setting (attempted or completed): _____

(e) Number of previous colonoscopies in the ***clinical*** setting (attempted or completed): _____

(f) Number of previous colonoscopies in the ***simulated*** setting (attempted or completed): _____

(g) Number of previous sigmoidoscopies in the ***clinical*** setting (attempted or completed): _____

(h) Number of previous sigmoidoscopies in the ***simulated*** setting (attempted or completed): _____

(i) Number of other ***clinical*** GI endoscopy procedures (please specify procedure): _____

_____
_____

(j) Number of other ***simulated*** GI endoscopy procedures (please specify procedure): _____
_____
_____

Competitiveness Scale

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
I like competition	1	2	3	4	5
I am a competitive individual	1	2	3	4	5
I enjoy competing against an opponent	1	2	3	4	5
I don't like competing against others	1	2	3	4	5
I get satisfaction from competing with others	1	2	3	4	5
I find competitive situations unpleasant	1	2	3	4	5
I dread competing against others	1	2	3	4	5
I try to avoid competing with others	1	2	3	4	5
I often try to outperform others	1	2	3	4	5
I try to avoid arguments	1	2	3	4	5
I will do almost anything to avoid an argument	1	2	3	4	5
I often remain quiet rather than risk hurting another person	1	2	3	4	5
I don't enjoy challenging others even when I think they are wrong	1	2	3	4	5
In general, I will go along with the group rather than create conflict	1	2	3	4	5

The General Self-Efficacy Scale

Please rate the following items based on a 4-rank scale.

1= Not at all true 2= Hardly true 3= Moderately true 4= Exactly true

	RATING
I can always manage to solve difficult problems if I try hard enough.	
If someone opposes me, I can find the means and ways to get what I want.	
It is easy for me to stick to my aims and accomplish my goals.	
I am confident that I could deal efficiently with unexpected events.	
Thanks to my resourcefulness, I know how to handle unforeseen situations.	
I can solve most problems if I invest the necessary effort.	
I can remain calm when facing difficulties because I can rely on my coping abilities.	
When I am confronted with a problem, I can usually find several solutions.	
If I am in trouble, I can usually think of a solution.	
I can usually handle whatever comes my way.	

Gamification User Types Hexad Personal Questionnaire

	Strongly Agree	Agree	More or less agree	Undecided	More or less disagree	Disagree	Strongly disagree
It makes me happy if I am able to help others	1	2	3	4	5	6	7
I like helping others to orient themselves in new situations	1	2	3	4	5	6	7
I like sharing my knowledge	1	2	3	4	5	6	7
The wellbeing of others is important to me	1	2	3	4	5	6	7
Interacting with others is important to me	1	2	3	4	5	6	7
I like being part of a team	1	2	3	4	5	6	7
It is important to me to feel like I am part of a community	1	2	3	4	5	6	7
I enjoy group activities	1	2	3	4	5	6	7
It is important to me to follow my own path	1	2	3	4	5	6	7
I often let my curiosity guide me	1	2	3	4	5	6	7
I like to try new things	1	2	3	4	5	6	7
Being independent is important to me	1	2	3	4	5	6	7
I like defeating obstacles	1	2	3	4	5	6	7
It is important to me to always	1	2	3	4	5	6	7

carry out my tasks completely							
It is difficult for me to let go of a problem before I have found a solution	1	2	3	4	5	6	7
I like mastering difficult tasks	1	2	3	4	5	6	7

I like to provoke	1	2	3	4	5	6	7
I like to question the status quo	1	2	3	4	5	6	7
I see myself as a rebel	1	2	3	4	5	6	7
I dislike following rules	1	2	3	4	5	6	7

I like competitions where a prize can be won	1	2	3	4	5	6	7
Rewards are a great way to motivate me	1	2	3	4	5	6	7
If the reward is sufficient I will put in effort	1	2	3	4	5	6	7
Return of investment is important to me	1	2	3	4	5	6	7

Endoscopy Knowledge Post-Test

This is the knowledge test for the University of Toronto endoscopic simulation course. Please type in your "endo" number to begin the test. The test consists of 17 questions for a total of 20 points.

The knowledge questions are on the next two pages. You have 30 minutes to answer these questions.

These answers are confidential, and your responses and score are only for the purposes of our research studies. They will not be used as part of your residency training assessments, or as part of competency assessments.

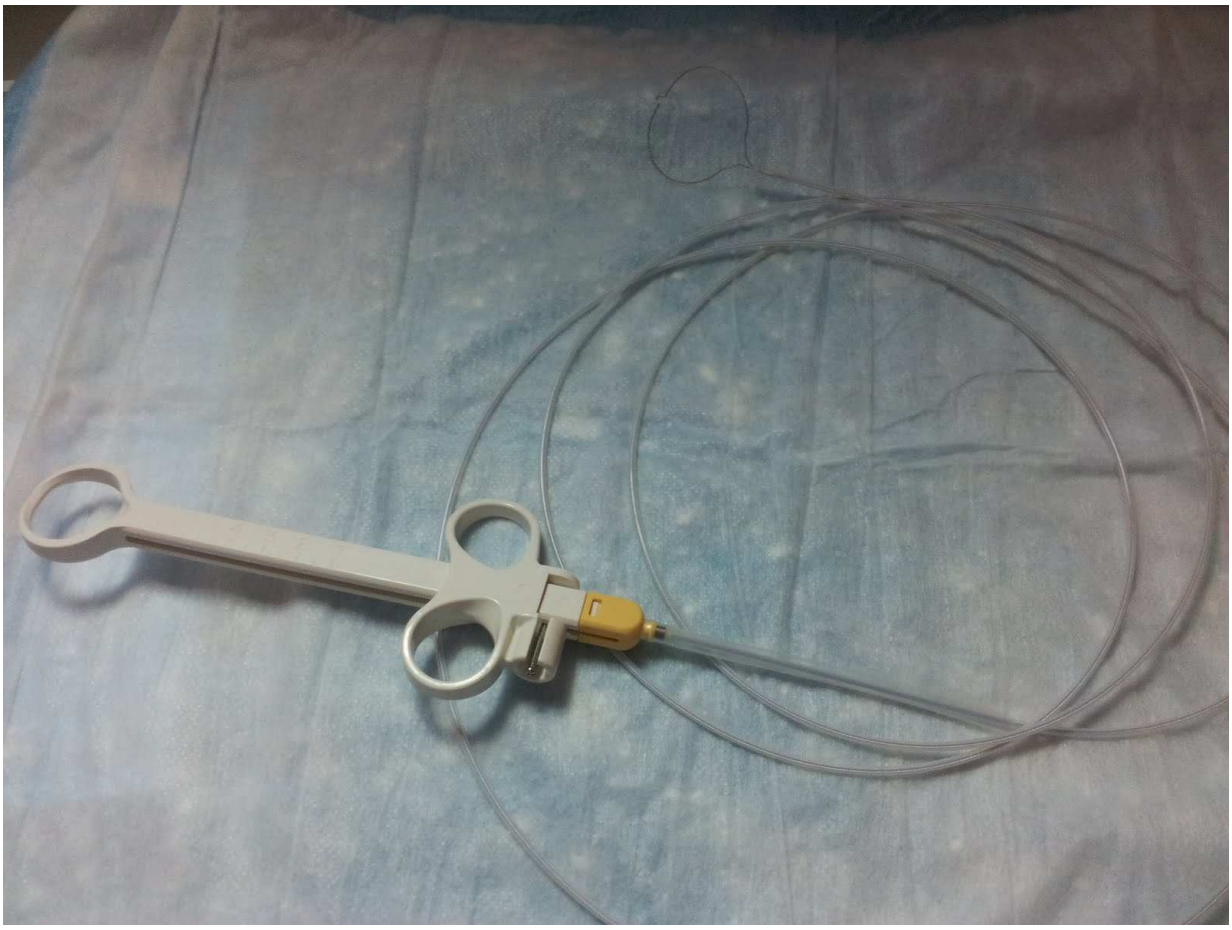
*Required

1. **Please type in your "endo" number login to start** *
   ie, "Endo10"

Endoscopic Knowledge Test (page 1 of 2)

2. **Question 1 (1 point)**
   Name the endoscopic device depicted below.
   Mark only one oval.

   - A. Endoloop
   - B. Endoscopic snare
   - C. Endoscopic biopsy forceps
   - D. Gold probe
   - E. Oval probe



3. **Question 2 (1 point)**

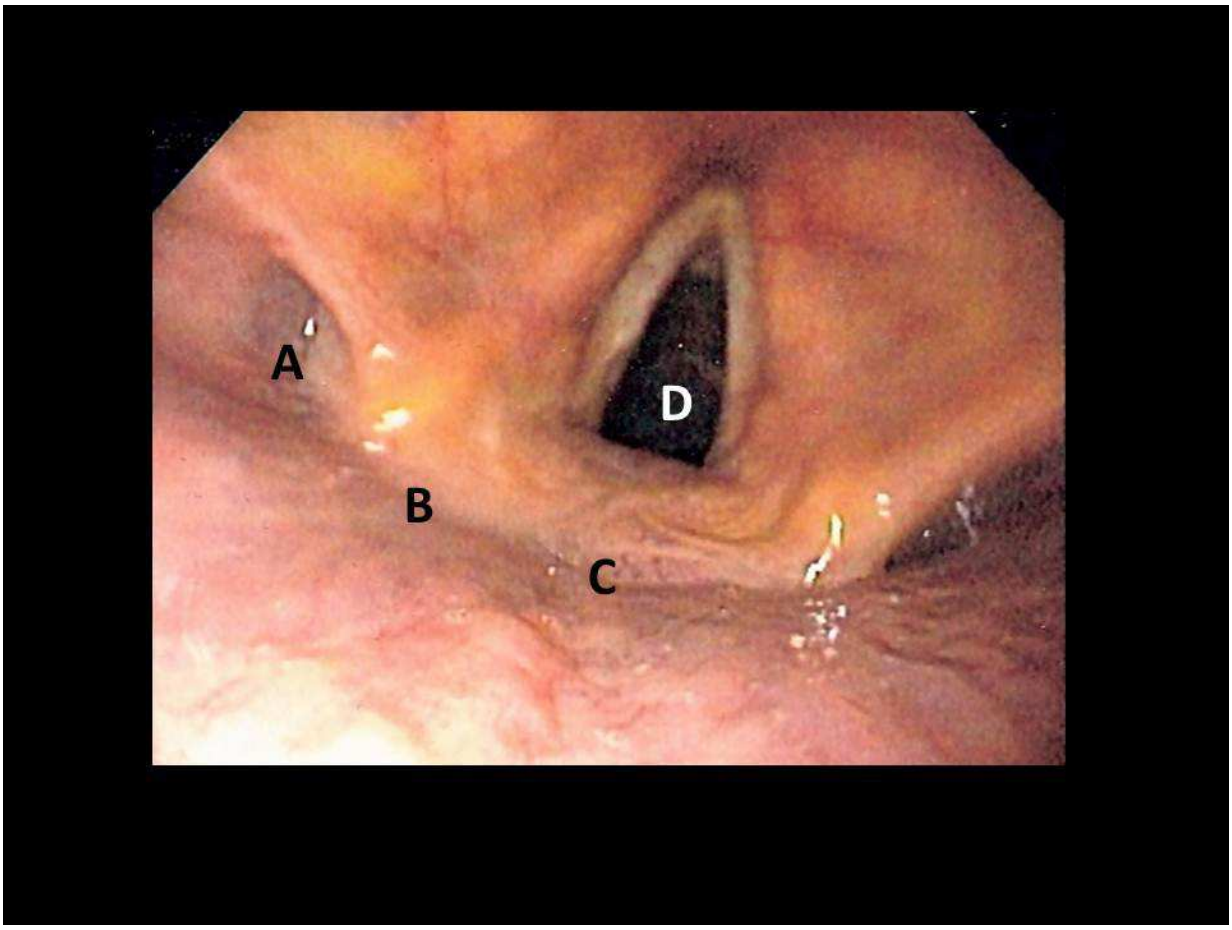
What type of sigmoid colon loop is most beneficial for entry into the descending colon?
Mark only one oval.

- A. Alpha-loop
- B. Reverse alpha-loop
- C. Gamma-loop
- D. N-loop
- E. Reverse-N loop

4. **Question 3 (1 point)**

Below is an endoscopic image of the larynx taken with a gastroscope. Which location is representative of the ideal place to position the gastroscope to intubate the esophagus?
Mark only one oval.

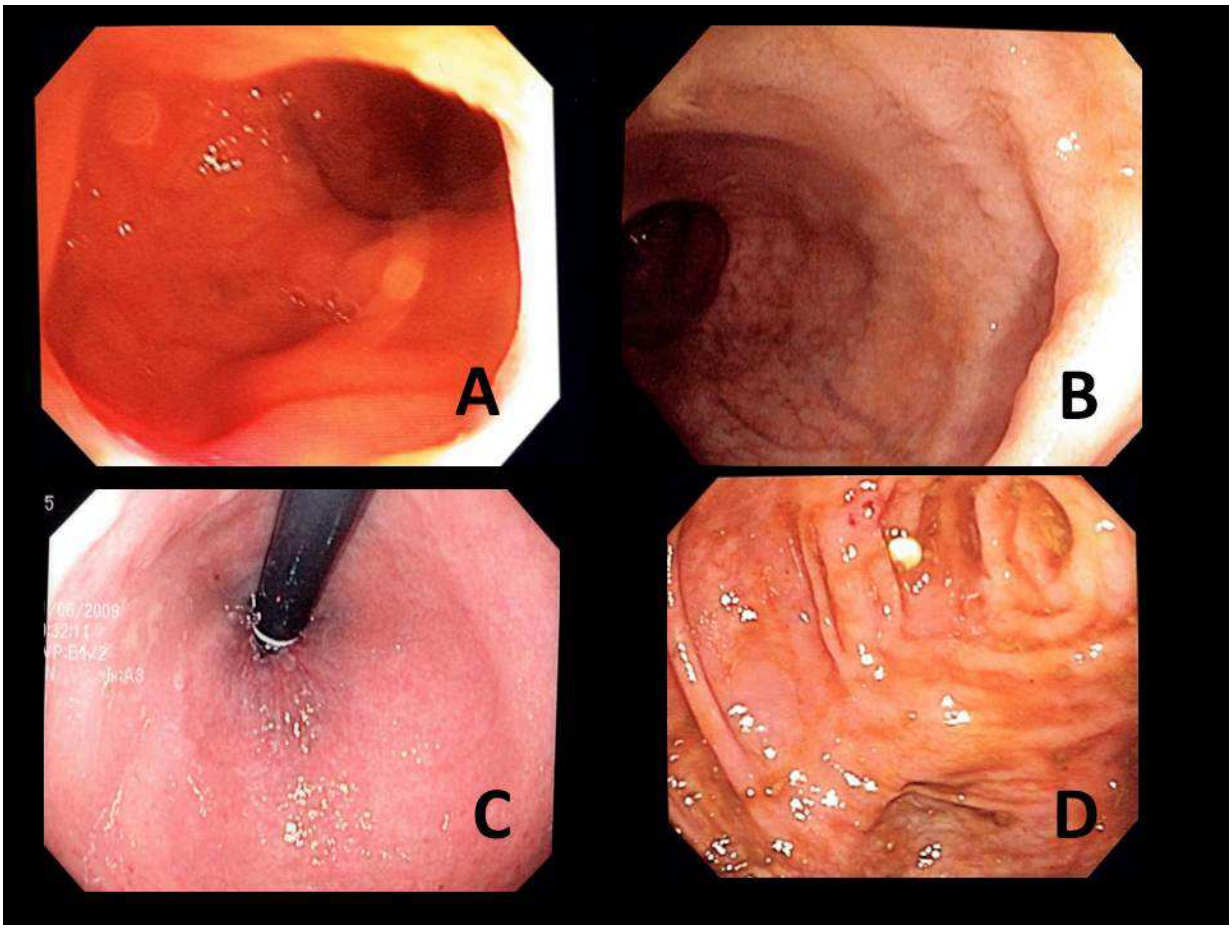
- A
- B
- C
- D



5. **Question 4 (1 point)**

Which of the images below is an endoscopic image of the cecum?
Mark only one oval.

- Image A
- Image B
- Image C
- Image D



6. **Question 5 (1 point)**

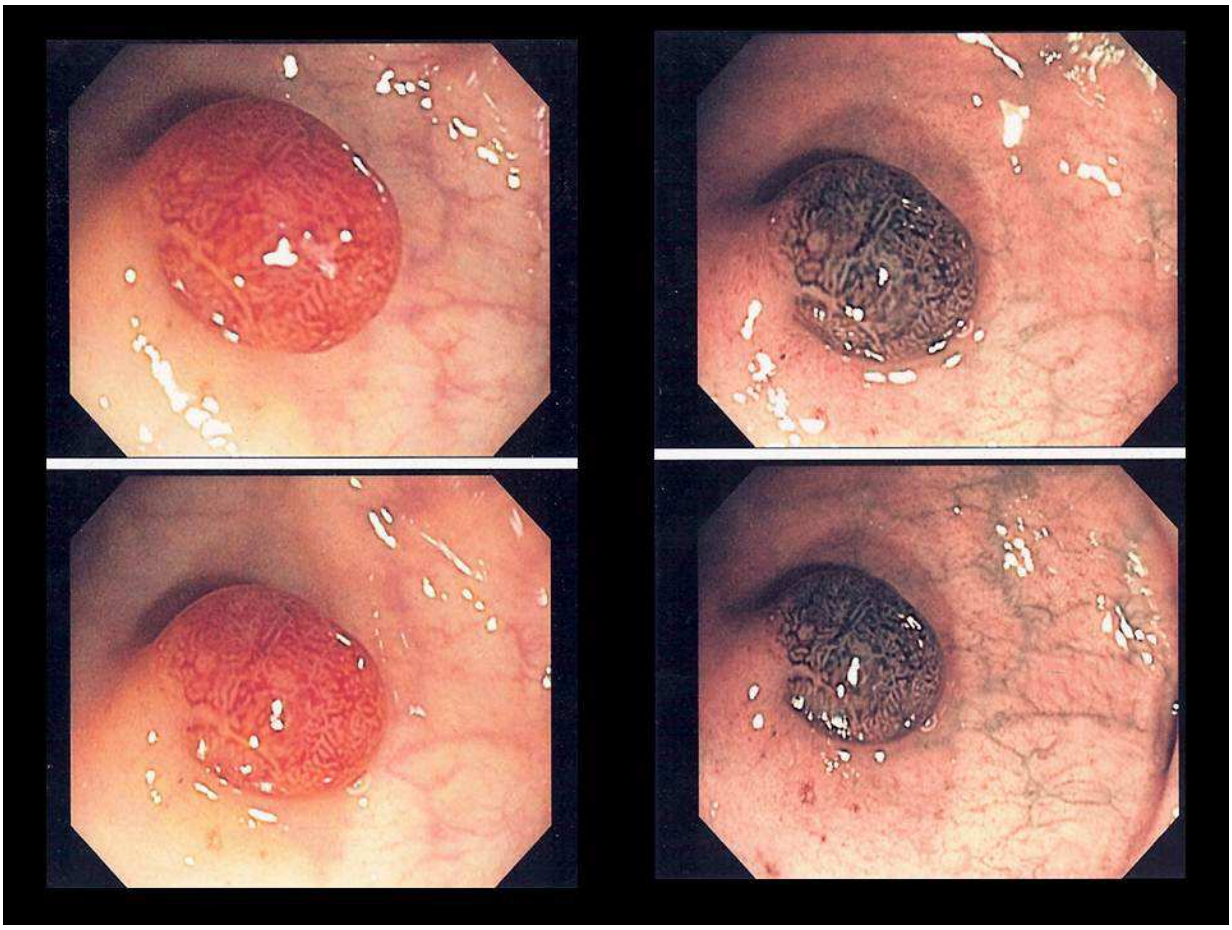
The pit pattern of polyps is commonly used as an endoscopic classification to determine the likely histopathology. What is the name of the classification most commonly used for pit patterns?
Mark only one oval.

- A. Kudo classification
- B. Maclean classification
- C. Yoshida classification
- D. Haggitt classification
- E. Sarin classification

7. **Question 6 (1 point)**

The pit patterns of the polyp depicted below have been enhanced by use of ambient light of blue-green wavelength (approximately 450 - 540 nm). What is the name of this technology?
Mark only one oval.

- A. Confocal microscopy
- B. Optical coherence tomography
- C. Chromoendoscopy
- D. FICE (Fuji intelligent chromoendoscopy)
- E. Narrow band imaging



8. **Question 7 (1 point)**

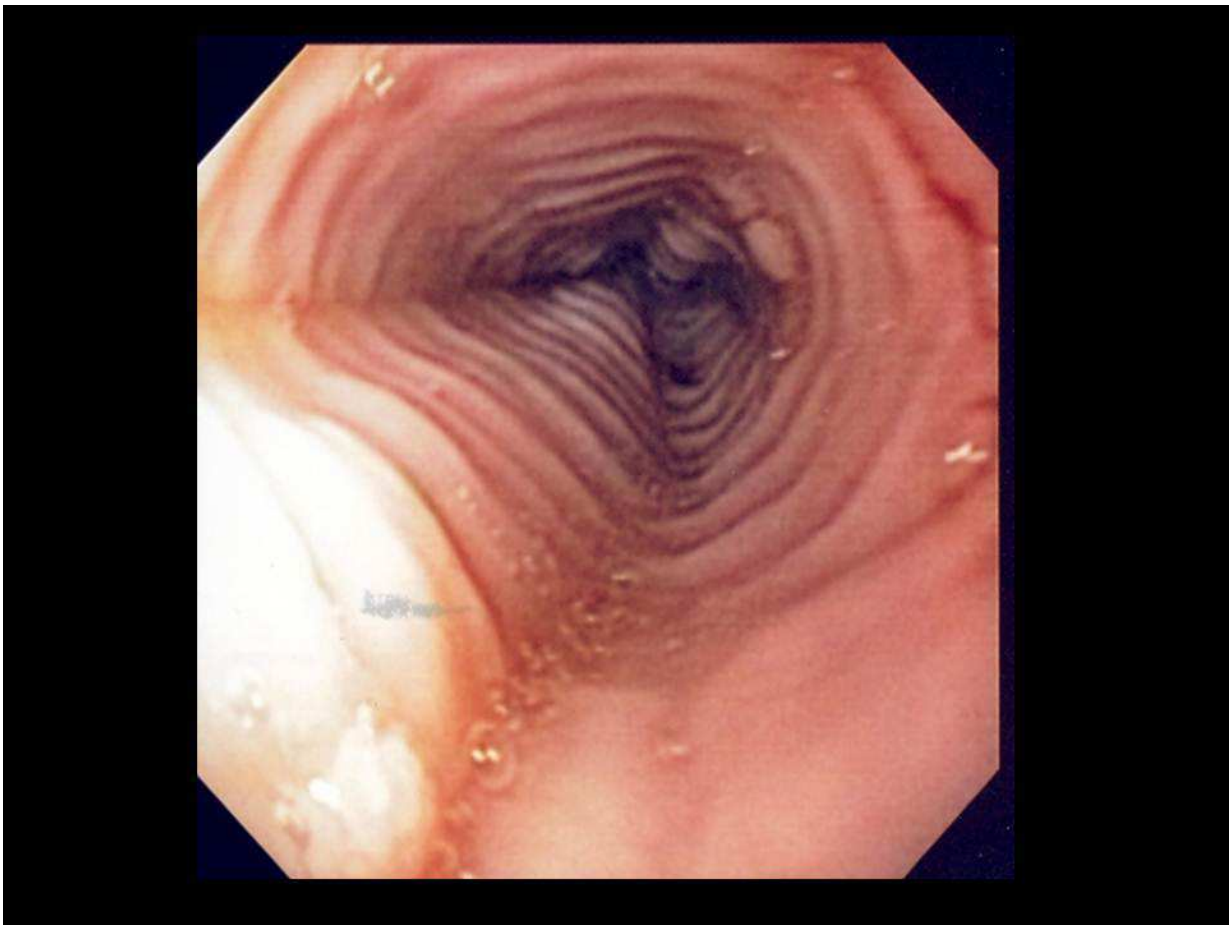
With a well prepared colonoscopy to the cecum performed by an experienced endoscopist, what is the approximate risk of missed advanced neoplasia?
Mark only one oval.

- A. 1%
- B. 3-5%
- C. 5-10%
- D. >10%

9. **Question 8 (1 point)**

Below is an endoscopic view of a patient's esophagus. What is the endoscopic diagnosis?
Mark only one oval.

- A. Eosinophilic esophagitis
- B. Radiation esophagitis
- C. Mosaic esophagus
- D. Barrett's esophagus
- E. Diffuse-type squamous cell carcinoma



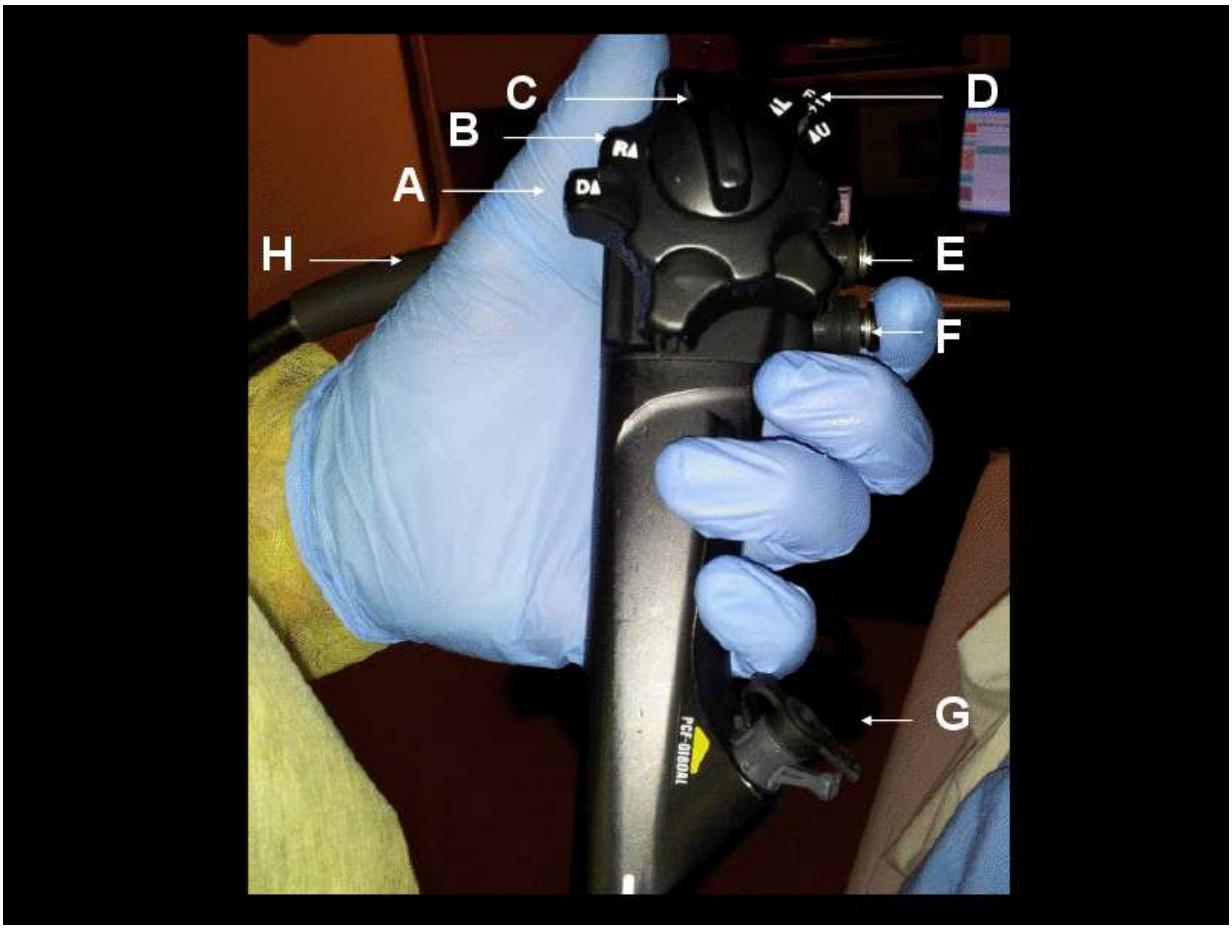
Endoscopy knowledge test (page 2 of 2)

10. **Question 9 (1 point)**

Which of the following is a commonly used bowel preparation score for colonoscopy?
Mark only one oval.

- A. Los Angeles bowel preparation score
- B. Ottawa bowel preparation score
- C. King's College bowel preparation score
- D. Chicago bowel preparation score
- E. Washington bowel preparation score

Question 10 (4 points)



Identify the labelled parts of the colonoscope head (4 points; 0.5 points each)

11. **A**

12. **B**

13. **C**

14. **D**

15. **E**

16. **F**

17. **G**

18. **H**

Question 11 (1 point)

Certain skills necessary for endoscopic performance may be independent of the technical performance of the procedure. Name four non-technical skills that you would view as important in the performance of endoscopic procedures.

19. **A**

20. **B**

21. **C**

22. **D**

23. **Question 12 (1 point)**

Which of the following is not a risk factor for colonic perforation at the time of colonoscopy
Mark only one oval.

- A. Barotrauma
- B. Mucosal injection
- C. Sigmoid looping
- D. Trainee endoscopist performing colonoscopy
- E. Resection of sessile polyp

24. **Question 13 (1 point)**

A 50 year old patient presents for a screening colonoscopy to your open access endoscopy unit. They have completed a 4L bowel preparation. Upon taking a history, you discover that they had a colonoscopy 2 years ago to work up anorectal bleeding but you don't have the results. What is the appropriate course of action?
Mark only one oval.

- A. Complete a screening colonoscopy because the indication of colorectal cancer screening is different than anorectal bleeding.
- B. Another screening colonoscopy is not needed; send patient home.
- C. Make concerted effort to track down report of prior colonoscopy and if not obtained, then proceed with screening colonoscopy.
- D. Make concerted effort to track down report of prior colonoscopy and if not obtained, then explain to patient that they can choose to defer procedure until report is obtained and reviewed
- E. Your endoscopic skills exceed that of the previous endoscopist and the procedure must be repeated.

25. **Question 14 (1 point)**

A unilingual Azerbaijani woman comes in for a gastroscopy to work up epigastric pain. She is unable to understand the consent process, which of the following is most correct?
Mark only one oval.

- A. Do a physical examination; if she has abdominal discomfort, continue with gastroscopy.
- B. Ask the patient's daughter to translate the consent form.
- C. Reschedule the gastroscopy and ask her to bring a translator.
- D. Reschedule the gastroscopy and arrange for a translator to accompany her.
- E. Obtain consent from daughter and proceed with procedure

26. **Question 15 (1 point)**

You are completing a screening colonoscopy and discover a 12 mm pedunculated polyp in the transverse colon. The endoscopy nurse suggests the use of a 10 mm snare and no electrocautery, but you believe a 15 mm snare with electrocautery would be more appropriate. What do you do?
Mark only one oval.

- A. Take the nurse's suggestion since he/she is more experienced than yourself.
- B. Use a 15 mm snare and ignore the nurse.
- C. Ask the nurse for the rationale for the smaller snare and the absence of cautery and verbalize your decision to proceed with the 15 mm snare with cautery.
- D. Discuss with the nurse why you wish to proceed with the larger snare and electrocautery before proceeding with the polypectomy.
- E. Call in a colleague to assist in the decision making.

27. **Question 16 (1 point)**

You are completing a polypectomy of a 2 cm Paris II-a (flat) polyp in the cecum of a 65 year old male. After the polypectomy you notice a perforation in the cecum. You aim to close the defect with endoclips, start antibiotics, and arrange imaging and possible surgery. Which of the following would not be appropriate?
Mark only one oval.

- A. Start the plan above for the management of the patient's complication, as soon as possible.
- B. Inform family members of the procedure's complications before proceeding with the above plan.
- C. Ensure airway, breathing and circulation are intact above all else.
- D. Call for extra assistance into the room as soon as possible.
- E. Stay calm as you manage the situation.

28. **Question 17 (1 point)**

You perform a screening colonoscopy on an anemic 50 year old male who complains of weight loss, altered bowel habits and blood in his stool. You identify the patient is suffering from colorectal cancer. Which one of the following would not be appropriate in explaining the results of the colonoscopy to the patient?
Mark only one oval.

- A. Ensure the results are delivered in a private setting
- B. Do not inform the patient of the suspected diagnosis until you have the pathology results
- C. Ensure to be empathetic during delivery of the results of the colonoscopy
- D. Establish that the patient understands the results after you explain it to them
- E. Be aware of the patient's reaction and tone as you are delivering the news

TEAMSTEPPS TEAMWORK ATTITUDES QUESTIONNAIRE

With respect to how each question applies to interactions with a team in ENDOSCOPY, please respond to the questions below by placing a checkmark in the box that corresponds to your level of agreement from Strongly Disagree to Strongly Agree. We realize that the questions may be a little vague but please select only one response for each question.

Team Structure

29. **1. It is important to ask patients and their families for feedback regarding patient care before/in/after endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

30. **2. Patients are a critical component of the care team in surgery and endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

31. **3. The Department of Surgery or Division of Gastroenterology influences the success of direct care teams in surgery and endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

32. **4. In surgery and endoscopy, the mission of the team is of greater value that the goals of individual team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

33. **5. Effective team members can anticipate the needs of other team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

34. **6. High-performing teams in health care share common characteristics with high-performing teams in other industries** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Leadership

35. **7. It is important for a surgeon-leader or GI-leader to share information with team members** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

36. **8. Leaders should create informal opportunities for team members to share information** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

37. **9. Effective leaders view honest mistakes as meaningful learning opportunities** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

38. **10. It is a leader's responsibility to model appropriate team behaviour** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

39. **11. It is important for surgeon-leaders or endoscopy-leaders to take time to discuss their team members' plans for each patient** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

40. **12. Team leaders should ensure that team members help each other out when necessary** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Situation monitoring

41. **13. Individuals can be taught how to scan the patient environment in the OR or procedure room for important situation cues.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

42. **14. Monitoring patients provides an important contribution to the effective performance of the team** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

43. **15. Even individuals who are not part of the direct care team should be encouraged to scan for and report changes in patient status** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

44. **16. It is important to monitor the emotional and physical status of other team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

45. **17. It is appropriate for one team member to offer assistance to another who may be too tired or stressed to perform a task** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

46. **18. Team members who monitor their emotional and physical status on the job are more effective** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Mutual support

47. **19. To be effective, team members should understand the work of their fellow team members.** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

48. **20. Asking for assistance from a team member us a sign that that individual does not know how to do his/her job effectively** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

49. **21. Providing assistance to team members is a sign that an individual does not have enough work to do** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

50. **22. Offering to help a fellow team member with his/her individual work tasks is an effective tool for improving team performance** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

51. **23. It is appropriate to continue to assert a patient safety concern until you are certain that it has been heard.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

52. **24. Personal conflicts between team members do not affect patient safety** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Communication

53. **25. Teams that do not communicate effectively significantly increase their risk of committing errors** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

54. **26. Poor communication is the most common cause of reported errors** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

55. **27. Adverse events may be reduced by maintaining an information exchange with patients and their families** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

56. **28. I prefer to work with team members who ask questions about information I provide** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

57. **29. It is important to have a standardized method for sharing information when handing off patients after endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

58. **30. It is nearly impossible to train individuals how to be better communicators** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

59. **Please indicate any additional comments in the space below.**

Thanks for your participation.

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Google Forms

Endoscopist Participant ID #: _____ Date (DD/MM/YYYY): _____ Start Time: _____

End Time: _____

Assessor: Self-Assessment VR Simulator (circle one): 1 2 3

VR Case: _____

ENDOSCOPIC NON-TECHNICAL SKILLS SELF-REFLECTION TOOL

	Y / N
1. Did I take a focused patient history?	
2. Did I review the patient's medications (i.e. anticoagulants) and allergies?	
3. Did I identify the correct procedure and take an appropriate consent?	
4. Did I discuss the sedation plan with the anesthetist or RN?	
5. Did I introduce the team and myself to the patient?	
6. Did I discuss the procedure with the patient and address concerns?	
7. Did I ask the team if they were ready to start?	
8. Did I situate the patient in the correct position?	
9. Did I verbalize/acknowledge relevant anatomy/landmarks?	
10. Did I check vital signs often (every few minutes)?	
11. Did I update the team and patient on the progress of the procedure?	
12. Did I address patient comfort (i.e. ask the patient where pain is) and enact a plan for a patient who was not comfortable?	
13. Did a secondary goal arise during the procedure (e.g. polypectomy)? Did I identify issues and problems that arose from this scenario? Did I verbalize the plan to attend to these?	
14. Did I use closed-loop communication when interacting with the team?	
15. Did I discuss results with the patient post-procedure (i.e. complication, what was found, etc.) and create a follow-up plan?	
16. Was I respectful toward the patient and team?	
17. Did I identify any errors I made afterward? If so what can I do to improve my performance?	


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M-OSANTS – NON-TECHNICAL SKILLS

SITUATIONAL AWARENESS: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to remain aware of the patient's history (e.g. allergies, medications, etc.)? Did the endoscopist review procedural details prior to procedure (e.g. confirms correct procedure)? Did the endoscopist demonstrate procedural planning (e.g. identifies objectives for the procedure at the start)? Did the endoscopist collect and use information during the procedure (e.g. change in vital signs)? Did the endoscopist recognize the scope of practice (e.g. refrain from unfamiliar procedures/ interventions)? Did the endoscopist anticipate potential problems during the procedure while proposing suitable solutions (e.g. proactively apply loop reduction strategies)? Was the endoscopist mindful of procedure time? Did the endoscopist ensure that patient outcomes are met (e.g. maintain patient comfort)? Did the endoscopist anticipate needs of team members and of the patient (e.g. minimize patient anxiety)?				

DECISION MAKING: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to implement endoscopic and clinical knowledge when making a decision (e.g. choosing equipment appropriate to endoscopic appearance)? Did the endoscopist identify issues and subsequently tailor a plan for resolution (e.g. application of loop reduction strategies)? Did the endoscopist confidently create a plan and articulate details of the plan to the team)? Did the endoscopist demonstrate understanding of the risks and benefits of an intervention/ maneuver (e.g. aware of bleeding risk due to polypectomy)? Did the endoscopist account for relevant patient information (e.g. mindful of contraindications)? Did the endoscopist appropriately delegate tasks to staff (e.g. requesting equipment from nurses)? Did the endoscopist enact a subsequent option if initial action unsuccessful? Did the endoscopist respond appropriately if the procedure extends out of the endoscopist's scope of practice (e.g. asking for assistance from senior staff)?				

COMMUNICATION: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to receive and respond to information from team members? Did the endoscopist actively limit distractions in the room (e.g. restricts cell phone use)? Did the endoscopist convey information using a closed-loop (e.g. confirms amount of sedation to be administered)? Did the endoscopist speak with clarity, while providing details when appropriate (e.g. requesting snare with specific size)? Did the endoscopist indicate a specific team member if there are multiple staff (e.g. addresses nurse by name)? Did the endoscopist use language appropriate for the recipient (e.g. minimizes medical jargon for patients)? Was the endoscopist aware of verbal tone and volume (e.g. speaks to staff in a respectful, collegial manner that can be heard)? Did the endoscopist ensure that the recipient understands information (e.g. patient comprehends risks)? Did the endoscopist relay findings to patient, including any adverse events (e.g. follow-up during aftercare)?				

LEADERSHIP: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to take responsibility for the process of the procedure (e.g. acknowledge mistakes)? Did the endoscopist direct the flow of the team process, including an appropriate delegation of labour (e.g. requesting that nurses attend to patient discomfort)? Did the endoscopist demonstrate confidence when leading the team, even under pressure (e.g. maintains composure during a bleed)? Did the endoscopist lead the endoscopic pause?				

PROFESSIONALISM: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Did the endoscopist demonstrate a respectful and courteous attitude towards the patient and team members (e.g. introduces himself/herself to everyone in the room)? Did the endoscopist acknowledge mistakes during procedure? Did the endoscopist display empathy for the patient (e.g. responds to patient discomfort)? Did he endoscopist advocate on behalf of the patient? Did the endoscopist manage time appropriately (e.g. mindful of endoscopy unit time)? Did the endoscopist ensure follow-up and address patient concerns within appropriate environment (e.g. follow-up within office or dedicated clinical area)? Did the endoscopist refrain from inappropriate conversations (e.g. does not discuss other patients during a procedure)? Did the endoscopist ensure that the procedure adheres to best-practice guidelines (e.g. record quality metrics)?				

TEAMWORK: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to act effectively within the team of nurses, technicians, management, and other physicians? Did the endoscopist demonstrate respect for all members of the team (e.g. speaks in a collegial, respectful tone)? Was the endoscopist aware of the roles of all members of the endoscopic team? Did the endoscopist display willingness to assist others, if appropriate (e.g. when transferring a patient)? Did the endoscopist ask for advice from other team members? Did the endoscopist take into account feedback from other team members (e.g. listens to suggestions for equipment)?				

Endoscopist Participant ID #: _____ Date (DD/MM/YYYY): _____ Start Time: _____

End Time: _____

Assessor: _____ VR Simulator (circle one): 1 2 3

VR Case: Polypectomy Case 3

Maximal distance reached (check one):

- ☐ Rectum
- ☐ Sigmoid
- ☐ Descending Colon
- ☐ Splenic Flexure
- ☐ Hepatic Flexure
- ☐ Ascending Colon
- ☐ Cecum
- ☐ Terminal Ileum

DOPS – TECHNICAL SKILLS

Please write the appropriate score from the scale below

Scale:
4 Highly skilled performance
3 Competent & safe throughout procedure, no uncorrected errors
2 Some standards not yet met, aspects to be improved, some errors uncorrected
1 Accepted standards not yet met, frequent errors uncorrected

CRITERIA	SCORE
Assessment, consent, communication	
• Obtains informed consent using a structured approach ○ Satisfactory procedural information ○ Risk and complications explained ○ Co-morbidity ○ Sedation ○ Opportunity for questions	**1 2 3 4**
• Demonstrates respect for patient's views and dignity during the procedure	**1 2 3 4**
• Communicates clearly with patient, including outcome of procedure with appropriate management and follow up plan. Full endoscopy report.	**1 2 3 4**
Safety and sedation	
• Safe and secure IV access (or indicates need)	**1 2 3 4**
• Gives appropriate dose of analgesia and sedation and ensures adequate oxygenation and monitoring of patient (or indicates does, need for monitoring)	**1 2 3 4**
• Demonstrates good communication with the nursing staff, including dosages and vital signs	**1 2 3 4**
Endoscopic skills	
○ Checks endoscope function before intubation (or indicates need to check)	**1 2 3 4**
○ Performs/Indicates need for PR	**1 2 3 4**
• Maintains luminal view / inserts in luminal direction	**1 2 3 4**
• Demonstrates awareness of patient's consciousness and pain during the procedure and takes appropriate action	**1 2 3 4**
○ Uses torque steering and control knobs appropriately	**1 2 3 4**
○ Uses distension, suction and lens washing appropriately	**1 2 3 4**
• Recognizes and logically resolves loop formation	**1 2 3 4**
○ Uses position change and abdominal pressure to aid luminal views	**1 2 3 4**
○ Completes procedure in reasonable time	**1 2 3 4**
Diagnostic and therapeutic ability	
• Adequate mucosal visualization	**1 2 3 4**
• Recognizes caecal/desc. colon landmarks or incomplete examination	**1 2 3 4**
• Accurate identification and management of pathology	**1 2 3 4**
• Uses diathermy and therapeutic techniques appropriately and safely	**1 2 3 4** ☐ **N/A**
• Recognizes and manages complications appropriately	**1 2 3 4** ☐ **N/A**

Appendix X: Badge Table

Requirement Needed	Standardized Hints	Setting	Hour
Complete a case in less than a minute	Complete a case in less than a minute	Low fidelity	Hour 1
Complete Low Fidelity	Complete all Low fidelity cases	Low Fidelity	Hour 1
Proper Torque (as determined by assessor)	Torque properly	Low Fidelity	Hour 1
Less than 10% time in red-out	Be careful how much time in red out you spend.	Intro 3/4	Hour 2
Less than 90% Air left in colon	Remove an appropriate amount of air from the colon	Intro 3/4	Hour 2
Over 90% visualization	Make sure to have enough visualize the colon	Intro ¾	Hour 2
Identify the Ulcerative Colitis	ID a diagnosis	Intro 5	Hour 3
Identify pseudomembranous colitis	ID a diagnosis	Biopsy 3	Hour 3
Successful biopsy of Crohn's patient	Use the biopsy forceps	Poly 4	Hour 3 or 4
Take a Photo of a Pedunculated Polyp	Take photos	Poly 1	Hour 4
Identification of location of Polyp (splenic flexure or _cm in)	Say what you see	Poly 3	Hour 4
Outline major risks in colonoscopy Minimum of 4/5 1. Infection 2. Perforation 3. Missed lesions 4. Sedation complications 5. Bleeding	Pros and Cons	Integrated Scenarios	Hour 5/6
Pain acknowledgement (administration of meds, empathetic statement)	"Pain"	Integrated Scenarios	Hour 5/6

No time in extreme Pain	Patient comfort is important	Integrated Scenarios	Hour 5/6
Do an endoscopic Pause 1. Indicate a pause 2. Revise case 3. Feedback from SN	“Pause”	Integrated Scenarios	Hour 5/6
Retroflex without assistance	“Rectum”	High Fidelity	Any
Intubate the TI	Make sure you finish the whole pathway	High Fidelity	Any

**Assessors please fill out*

NURSE ASSESSED PATIENT COMFORT SCORE (NAPCOMS)

Domain	Item	0	1	2	3	Score
Pain	1- Intensity	None or minimal	Mild	Moderate	Severe	
	2- Frequency	None	Few (1 or 2 episodes)	Several times (3-4 episodes)	Frequent (>4 episodes)	
	3- Duration	None	Short duration (episode <30 seconds)	Moderate duration (30 sec-1 minute)	Long duration (episode lasts >1 min)	
	Total Pain Score (Intensity + Frequency + Duration)					
Sedation	Level of consciousness*	Alert	Sleepy but initiates conversation	Responds only when asked or stimulated	Unresponsive or only responds with pronounced simulation	
Global	Tolerability*	Very well tolerated	Reasonably well tolerated	Just tolerated	Poorly tolerated	

*Note: level of consciousness and tolerability are not used in overall score

Cognitive Load Index for Colonoscopy

CRITERIA	SCORE
Intrinsic load items: Please rate your agreement with the following statements regarding the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. Physically manipulating and controlling the colonoscope was difficult	**0 1 2 3 4 5 6 7 8 9 10**
2. Using ancillary instruments (i.e. biopsy forceps, polypectomy snare) was difficult	**0 1 2 3 4 5 6 7 8 9 10**
3. Identifying normal anatomy and/or landmarks was difficult	**0 1 2 3 4 5 6 7 8 9 10**
4. The endoscopic findings were complex or difficult to characterize	**0 1 2 3 4 5 6 7 8 9 10**
5. It was difficult to manage identified pathology (i.e. polyps that were difficult to remove, bleeding that was difficult to control)	**0 1 2 3 4 5 6 7 8 9 10**
6. It was difficult to keep track of, or remember, all the endoscopic findings	**0 1 2 3 4 5 6 7 8 9 10**
7. Managing the patient's level of comfort was difficult	**0 1 2 3 4 5 6 7 8 9 10**
8. Overall, this colonoscopy was difficult and/or complex	**0 1 2 3 4 5 6 7 8 9 10**
Extraneous load items: Please rate your agreement with the following statements regarding your experience during the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. My supervisor's instructions were unclear	**0 1 2 3 4 5 6 7 8 9 10**
2. My supervisor used language that was confusing or unfamiliar	**0 1 2 3 4 5 6 7 8 9 10**
3. The manner in which my superior provided instructions	**0 1 2 3 4 5 6 7 8 9 10**
4. I felt distracted by other people present in the endoscopy room	**0 1 2 3 4 5 6 7 8 9 10**
5. I felt distracted by the environment (i.e. my pager going off, environmental noise)	**0 1 2 3 4 5 6 7 8 9 10**
6. I felt distracted by things on my mind unrelated to this colonoscopy	**0 1 2 3 4 5 6 7 8 9 10**
Germane load items: Please rate your agreement with the following statements regarding your level of mental effort during the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. I invested substantial mental effort learning how to control or manipulate the colonoscope and/or other endoscopic equipment	**0 1 2 3 4 5 6 7 8 9 10**
2. I invested substantial mental effort identifying or understanding colonic anatomy	**0 1 2 3 4 5 6 7 8 9 10**
3. I invested substantial mental effort understanding, remembering and/or managing the endoscopic findings	**0 1 2 3 4 5 6 7 8 9 10**
4. I invested substantial mental effort learning how to manage patient comfort level	**0 1 2 3 4 5 6 7 8 9 10**
5. Overall, I invested substantial mental effort learning during this colonoscopy	**0 1 2 3 4 5 6 7 8 9 10**

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Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a consent form regarding the above mentioned research study. Before you give your consent to voluntarily participate in this study, it is important that you read the following information and ask the study personnel as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
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Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Background and Purpose of the Study

Colonoscopies are medical procedures that gastroenterology physicians and general surgeons learn during their residency training. Traditionally, these procedures are learned for the first time on patients in the clinical setting under the supervision of a fully-trained attending physician. Virtual reality (VR) has since been used to create devices, called endoscopic simulators that can emulate the look and feel of performing colonoscopies, and have been validated in research studies to confer basic skills to trainees. The optimal method to use virtual reality simulators for teaching trainees that have yet to begin procedures in colonoscopy has yet to be determined, and was identified by the American Society for Gastrointestinal Endoscopy as a need for further training.

The primary objective of this project is to evaluate the impact of a simulation-based training curriculum using gamification on clinical performance in colonoscopy.

Eligibility

You are asked to consider taking part in this study if you are a resident in General Surgery, Adult Gastroenterology or Pediatric Gastroenterology at the University of Toronto.

In order to be eligible for this study, you must be a post-graduate trainee in the above programs, must have completed less than 25 colonoscopic procedures, and must have completed less than 25 simulated colonoscopy procedures to date.

Description of the Study

We aim to recruit 36 postgraduate novice endoscopists from the Adult Gastroenterology, Pediatric Gastroenterology and General Surgery training programs at the University of Toronto. **Note:** this study takes place concurrently alongside the Annual Endoscopic Simulation Training Course. The study, as described below, is a randomized control trial that is investigating the effectiveness of a new simulation-based curriculum. The Annual Endoscopic Simulation Training Course is an educational program through the University of Toronto, which aims to teach novices how to perform colonoscopies. Participation in the study component is optional; if you chose to opt-out of the study, it will not impact your participation in the course.

You will be asked to take a written questionnaire at the start of the study to collect demographic and background information including: age, sex, level of training, previous endoscopy experience and nature of experience, and video game experience, which may correlate with baseline endoscopic skill.

Following this you will take part in a pre-test consisting of the following:

1. **Knowledge Test:** A 30 minute (17 questions) multiple-choice question test designed to assess participants' theoretical knowledge of colonoscopy, including indications, sedation, safety, findings, pathology and follow-up.

2. VR Simulation Test: This test will assess baseline endoscopic technical proficiency through the completion of a colonoscopy procedure on the VR simulator (EndoVR® Colonoscopy Module 3). This scenario simulates a screening colonoscopy, without the need for any type of intervention (such as biopsy). The time limit of the procedure will be 30 minutes. An expert rater will be present to assess performance, but will not provide assistance. You will be videotaped in order to obtain performance measures, such that your faces are not captured (to ensure anonymity). Prior to starting the procedure, you will complete a questionnaire to measure self-efficacy.

3. VR Simulation Based "Integrated Scenario" Test: Following the simulator-only test, participants will complete an Integrated Scenario format test to assess their baseline endoscopic non-technical proficiency. This simulated procedure will mimic the setup of an endoscopic suite, as the VR simulator will be positioned next to a patient bed. A standardized patient, who will receive instructions regarding their medical role, will act out a scenario on colon cancer screening. You will be expected to explain the colonoscopy procedure, its benefits and risks, and to obtain procedural consent. You will then carry out the procedure on the VR simulator (EndoVR® Polypectomy Module #3) while responding to the patient and interacting with the standardized nurse (SN) as appropriate. The Standardized Patient (SP) will act out cues from the VR simulator if the simulator signals that the procedure has exceeded its threshold for discomfort. Your performance will be videotaped (in a manner that their faces are not captured to ensure anonymity) in order to obtain performance measures. You will be given a maximum of 45 minutes to complete the procedure.

You will then be randomized, using an online randomization algorithm, to one of two groups:

1. Control Group: This group will receive 4 hours of interactive small-group didactic and hands-on sessions. During these sessions, participants will focus on learning about the theory of colonoscopy, including related concepts of pathology, anatomy, and therapeutic technique. The last session will focus on non-technical skills (NTS) relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. During this session, participants will also watch a video that demonstrates an ideal endoscopic procedure in terms of NTS, as well as learn about the "E-NTS Checklist", which will be provided for them to later use during the integrated scenario training. This checklist has been developed according to evidence-based recommendations and targets non-technical skills. After each didactic session, a short MCQ based on the topics covered in that session will be administered, in keeping with suggestions from the literature regarding "test-enhanced learning". In addition to didactic training, the control group will be given six hours of expert-assisted instruction on both the low-fidelity simulator (1 hour) and on the high-fidelity VR simulator (5 hours). Six modules of increasing difficulty in colonoscopy and colonoscopic polypectomy will be taught using one-on-one feedback from an expert academic endoscopist. The endoscopy instructor will demonstrate techniques, answer

questions and provide individualized performance feedback on global performance, with a focus on non-technical skills. During training on the high-fidelity simulator, the last two hours will take the form of the integrated scenario, which will feature a standardized patient (SP) and standardized nurse (SN). Terminal feedback will be given after each integrated scenario by the instructor. Finally, the "E-NTS Checklist" will be accessible during training in the integrated scenario, as participants can view the checklist prior to each case and review it after the case.

2. Intervention Group: This group will receive the same 4 hours of didactic teaching, and hands-on sessions. The intervention group will also receive the same teaching on both the low-fidelity and high-fidelity simulators. Within the context of the didactic sessions and simulator training, the GIC group will engaged in "gamified practice" in two ways. First, leaderboards will also be used to track and rank participants' performances. Prior to training, participants in the GIC group will watch a tutorial video on the functionality of the leaderboards and subsequently receive an anonymized ID tag that can be used to identify only their position on the leaderboard. Participants will also be informed that awards will be given to the individual who achieves first place. An "introductory" leaderboard, based on technical skills performance during the low-fidelity simulator practice, will be used to familiarize participants with the function of the leaderboard. After practice on the low-fidelity simulator is completed, participants will be introduced to the leaderboard for performance on the VR simulator and didactic sessions. Specifically, this leaderboard will include 4 components: a non-technical skills score, a technical skills score, a cognitive skills score,and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the M-OSANTS and JAG-DOPS, respectively, while the scoring of the cognitive skills will be based on percentage scores of the MCQ from the didactic sessions. Scores will be aggregated only from participants training on the same days. The leaderboard will be displayed on a central laptop and/or TV screen and will be accessible at any time throughout the day. Finally, participants in the GIC group will have the opportunity to be rewarded for their performances. One method of reinforcing good performance will be through achievement badges. These badges will be awarded after each scenario on the high-fidelity simulator and will be based on completion, proper technique, and/ or correct identification of pathology. Additionally, the participant who has accumulated the most badges will be awarded a prize.

A post-test will be administered after completion of the training period to compare learning between the two groups, consisting of:

1. Knowledge Test

Knowledge acquisition will be evaluated using a 30 minute (17 questions) multiple-choice question test designed to assess theoretical knowledge of colonoscopy.

2. Simulation-based Assessment

You will be assessed through the completion of a colonoscopy procedure on the VR simulator. As with the pre-test, the post-test will include an "integrated scenario" which links a standardized patient with the VR colonoscopy simulator. You will once again be required to explain the procedure, its benefits and risks, and obtain informed consent. You will then carry out the procedure on the simulator while responding to the patient as appropriate. Once again, the performance of all participants will be videotaped, such that their faces are not captured to ensure anonymity, in order to obtain performance measures.

3. Patient-based transfer test

You will then be contacted to undertake two colonoscopies on real patients. These procedures will be videotaped in a manner that anonymizes you and the patient. The videotapes will be assessed by two independent blinded expert endoscopists.

Potential Harms (Injury/Discomfort/Inconvenience)

There are no known harms associated with participation in this study.

Potential Benefits

You will not receive credit in performing colonoscopies by participating in this study. You may receive no direct benefits from being in this study. Results from this study will be used to adjust the structure and format of the current University of Toronto virtual-reality colonoscopy training curriculum for novice endoscopic trainees.

Confidentiality and Privacy

All the persons associated with this study, including the study investigators and delegates (study team) are committed to respecting your privacy. No information that discloses your identity will be published or released to any other persons without your consent unless required by law.

Video-recordings of your face are considered to be identifying personal information and will not be shown when videotaping these procedures. During the video-recordings, you are requested not to state your name or the names of anyone else or any institutions. However if this does happen, you should know that the audio track from the video will be removed so identifying information is removed.

Any records, documentation, or information related to you will be coded by study numbers to ensure that persons outside of the study will not be able to identify you. All study data forms will be identified by study code number and not by name. No identifying information about you will be allowed off site. All information that identifies you and study data will be securely stored at St. Michael's Hospital. The video recordings will be securely destroyed after data collection. Other identifying information will be securely destroyed after all the colonoscopy procedures have been completed. The study

data will be securely destroyed when the study results have been published, within five years after completion of the study.

It is important to understand that despite these protections being in place, experience in similar studies indicates that there is the risk of unintentional release of information. The principal investigator and study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will accidentally be given to someone else is minimal.

Data collected during this study will not form any part of your evaluation for the rotation and will not be forwarded to your program director or any other individual involved in your evaluation in residency. The study investigators will have access to the coded study data, but will not have access to your identifying information, including the video-recordings. The St. Michael's Hospital Research Ethics Board may have access to your identifying information and study data collected, for the purpose of study monitoring.

In no way does signing this consent form waive your legal rights nor release the investigators or involved institution from their legal and professional responsibilities.

Voluntary Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw or are withdrawn from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Study Results

We may present this study at a scientific conference and we intend to write an article about this study for a scientific journal. No identifying information about you will be revealed in any presentation or publication about the study. Study results will be communicated to you by request following completion of the study. You can ask for a copy of the published article by contacting Michael Scaffidi, Research Assistant, at (416) 864-5628 or by e-mail at scaffidim@smh.ca.

Potential Costs of Participant and Reimbursement to the Participant

Participating in this study will not result in any costs charged to you, and as such, no reimbursements or compensation will be provided.

Sponsor

This study is funded by a grant from the University of Toronto.

Compensation for Injury

If you suffer a physical injury from (the procedure(s) or participation) in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your participation in the Annual Endoscopic Simulation Course, clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Can Participation in this Study End Early?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact the Research Coordinator, Michael Scaffidi, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions

Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, you may contact the Chair of the Research Ethics Board, St. Michael's Hospital at 416-864-6060 ext. 2557 during regular business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

Study Contacts

If you require further information, or have any questions concerning this study, please contact the principal investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Collect calls will be accepted.

You may also contact the research assistant, Michael Scaffidi, at (416)-864-5628 or by e-mail at scaffidim@smh.ca.

You will be given a copy of this consent form to keep for your own records.

Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

Principal Investigator
Samir C. Grover, MD, MEd, FRCPC
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Declaration of Consent

The research study has been explained to me, and any questions that I have asked about the study have been answered to my satisfaction. A member of the study team, who has no influence on my academic program, will be obtaining my consent form. I have the right not to participate and the right to withdraw from this study without affecting my participation in the Annual Endoscopic Simulation Course, evaluation or standing on my academic program at the University of Toronto, or any admission to (or current status in) a residency/fellowship program. I have also been informed that my choice will not affect my current or future employment at St. Michael's Hospital. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators or involved institution from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me in this study will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission unless required by law. I have been given sufficient time to read the above information. I consent to participate in this study. I will be given a signed copy of this consent form.

Name of Participant (print)	Signature	Date

I have explained the study to the above-named participant and discussed the potential risks and benefits (if any) associated with participation in this research study. I have answered all questions asked with respect to this research study.

Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Consent Discussion	Date

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CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
Patient participants

This is a consent form regarding the above mentioned research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Before you give your consent to be a volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

CONFLICTS OF INTEREST
We have no known actual, apparent, potential or perceived conflicts of interest in conducting this study.

FUNDING SOURCE

This study is funded by a grant provided by the University of Toronto, Division of Gastroenterology.

PURPOSE OF THE RESEARCH
You are being asked to consider participating in this study because you are booked to have a colonoscopy.

Colonoscopy is a technically challenging procedure and it requires considerable training to learn the skill. Increasingly trainees that learn these skills are learning them on high-fidelity virtual reality simulators that have been designed to teach colonoscopy, prior to performance on real patients. Although simulation-based practice is being integrated into endoscopy training curricula, there is no consensus on the best way to how to do this. One method that has been used in surgical simulation is to interlace a lecture-based curriculum with supervised procedures with feedback with experts. It is unknown whether this provides better learning than self-directed endoscopic procedural learning.

The purpose of this study is to compare performance on colonoscopies performed on a virtual reality endoscopic simulator between two groups of beginning endoscopists, one trained with a curriculum that using gamficiation and one trained with a curriculum that uses conventional simulationtraining.

DESCRIPTION OF THE RESEARCH

WHAT WILL HAPPEN DURING THIS STUDY?

Two physician assessors will be asked to evaluate the performance of the physician performing your colonoscopy. In order to assess the performance, videotaping is required. The physicians will use standardized tests for performance of colonoscopy in order to perform the assessment. To ensure anonymity, your face and the endoscopist's face will not be recorded. Two views of the procedure will be captured at the same time: 1) a close-up view of the endoscopist's gloved hands using the control knobs and tube of the colonoscope and 2) the view obtained by the colonoscope's camera which shows the inside of the your bowel.

You will be asked, in person, to provide some personal health information including your age, gender, the reason why you having the colonoscopy procedure and if you have any history of a difficult colonoscopy or if you have had surgery in the past to remove part of your bowel.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

It is anticipated that about 120 people (80 patients and 40 endoscopists) will participate in this study at St. Michael's Hospital. The study is expected to take three years to complete.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

All data will be collected during your scheduled colonoscopy procedure time. Participation in this study will take no additional time and the duration of your colonoscopy procedure itself will not be affected.

If you decide to participate in this study you will be asked to do the following:

(1) Provide one of the study investigators, in person, with some personal health information including your age, gender, the reason why you are having the colonoscopy procedure and if you have any history of a difficult colonoscopy or have had surgery in the past to remove part of their bowel.

(2) Agree to allow your colonoscopy procedure to be videotaped during this study. Your name and face will not be shown to the camera.

POTENTIAL HARMS (Injury, discomfort, inconvenience)

You may experience side effects from participating in this study. Some of these risks we know about. There is also the possibility of risk that we do not know about or have not seen in study subjects to date. Some of these can be managed. If you decide to take part in this study, you should contact Dr. Samir C. Grover (Division of Gastroenterology, St. Michael's Hospital, 416-864-5628) if you think you have side effects even if you think it has nothing to do with the study.

The risks we know of are:

There are no direct short- or long-term risks anticipated. Data collected will be kept completely confidential and anonymous. Even though the risk that a participant's data could become public is very small, it can never be completely eliminated. However, every precaution is taken to prevent this. Any data collected during the study (e.g. performance assessments, videotaped performance) will be identified using only an individualized number known only to the principal investigator (Drs. Grover) so that your privacy is protected.

POTENTIAL BENEFITS

There is no benefit to you from your participation in this study.

PROTECTING YOUR INFORMATION

You have the right to have any information about you that is collected, used or disclosed for this research study to be handled in a confidential manner. No information that discloses your identity may be released or published without your consent. All information obtained during the study will be held in strict confidence. Even though the risk that your data could become public is very small, it can never be completely eliminated. However, every precaution is taken to prevent this. Prior to starting the study, you will be assigned a unique code known only to the principal investigator (Dr. Grover) so that your privacy is protected. Any data collected during the study will be identified using only this code.

The file which links your unique study identifier with your name is the only source of information that could possibly be utilized, either alone or with other information, to identify you. This encrypted file will be kept behind locked doors in Dr. Samir Grover's office, St. Michael's Hospital until data analysis is complete (anticipated time frame: 5 years). After that time it will be securely destroyed as per hospital requirements. Only Dr. Grover (principal investigator) will have access to this file.

Any study data about you that is sent outside of the hospital will be aggregate data for research presentations and publications. No individual level data will be reported .

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, including personal health information, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. Experience in similar studies indicates that the

greatest risk in this study to you is the unintentional release of information from your health records. The study doctor will protect your records and keep confidential all the information in your study file, including your name, address and telephone number. The chance that this information will accidentally be given to someone else is small.

You have the right to have any information about you and your health that is collected, used or disclosed for this research study to be handled in a confidential manner.

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your name, address, date of birth, new or existing medical records, that includes types, dates and results of medical tests or procedures.

Access to your personal health information will take place under the supervision of the Principal Investigator. The information that is collected for the study will be kept in a locked and secure area by the study doctor for 5 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the St. Michael's Hospital Ethics Board, a group of people who oversee the ethical conduct of research studies at St. Michael's Hospital

The investigators plan to publish the results of this study. You will not be named in any reports, publications, or presentations that my come from this study. Only group data will be presented.

STUDY RESULTS

As mentioned, the investigators plan to publish the results of this study. Once the study has been completed, you can contact Dr. Samir C. Grover (416-864-5628) to obtain a copy of the results.

POTENTIAL COSTS OF PARTICIPATION AND REIMBURSEMENT TO THE PARTICIPANT

You will not have to pay for any of the procedures involved in this study. There is no reimbursement associated with participation in this study.

COMPENSATION FOR INJURY

If you suffer a physical injury from participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study investigators, sponsors, or other involved institutions from their legal and professional responsibilities.

PARTICIPATION AND WITHDRAWAL

Participation in any research study is voluntary. If you choose to participate in this study, you can change your mind without reason and withdraw from the study any time up to 5 years. After 5 years, your data will be anonymized and it will no longer be possible to identify which data are yours. In addition, it you decide to decline participation or withdraw from the study at any time, this will have no impact on the care you or your family will receive at St. Michael's Hospital.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact Dr. Samir C. Grover, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions.

RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding your rights as a research participant, you may contact Chair of the Research Ethics Board at 416-864-6060 ext. 2557 during business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

STUDY CONTACTS

If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Samir C. Grover at 416-864-5628.

INFORMED CONSENT

Study Title: Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

Principal investigator: Dr. Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology, Department of Medicine
St. Michael's Hospital, University of Toronto
416-864-5628 (available Mon to Fri 9:00 AM – 5:00 PM)

The research study has been explained to me and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions of their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that study records relating to me will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told that I will be given a signed copy of this consent form.

_____ _____
Signature Date

☐ I **agree** to allow my colonoscopy procedure to be videotaped during this study as described in this consent form.

☐ I **do not agree** to allow my colonoscopy procedure to be videotaped during this study as described in this consent form.

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____ _____ _____
Name of person obtaining consent (print) Signature Date

ASSISTANCE DECLARATION □ (check here if not applicable)

The participant/substitute decision-maker was assisted during the consent process as follows (please check the relevant box and complete the signature space below):

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered..

I have been requested to interpret the consent discussion for the potential research participant (_____). I am competent in the English language and in the language of choice of the potential participant (_____). I am not involved in the research study. I agree to keep confidential all personal information of the potential participant. I have interpreted the consent discussion. The potential participant has advised me in his/her own language that he/she has been informed about the research study, the nature and extent of his/her participation, including the risks involved. The potential participant freely gives his/her consent to participate in this study.

_____	_____	_____	_____
Printed Name of Interpreter	Signature	of Interpreter	Date

_____	_____
Relationship or Position of Interpreter	Contact Information of Interpreter

☐ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant/substitute decision-maker.

_____	_____	_____ Print
Name of Witness	Signature	Date

_____

Relationship to Participant

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Protocol for a randomized trial evaluating the effect of applying gamification to simulation-based endoscopy training

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Protocol for a randomized trial evaluating the effect of applying gamification to simulation-based endoscopy training

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Author Contributions

Study conception and design: Scaffidi, Pearl, Walsh, Kalaichandran, Lin, Grover
Data acquisition: Scaffidi, Khan, Walsh, Winger, Kalaichandran, Lin, Grover
Analysis and interpretation of data: Scaffidi, Khan, Walsh, Grover
Drafting of the manuscript: Scaffidi, Khan, Walsh, Grover,
Critical revision of the manuscript for important intellectual content: Scaffidi, Khan, Walsh, Pearl, Winger, Kalaichandran, Lin, Grover
Final manuscript approval: Scaffidi, Khan, Walsh, Pearl, Winger, Kalaichandran, Lin, Grover

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Declarations: The authors have no conflicts of interest to declare.

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Abstract

Background: Simulation-based training provides a safe environment and effective means to enhance skills development. Simulation-based curricula have been developed for a number of procedures, including gastrointestinal endoscopy. Gamification, which is the application of game-design principles to non-game contexts, is an instructional strategy with potential to enhance learning. No studies that have investigated the effects of a comprehensive gamification curriculum on the acquisition of endoscopic skills among novice endoscopists.

Methods and analysis: Thirty-six novice endoscopists will be randomized to one of two endoscopy simulation-based training curricula: (1) the Conventional Curriculum Group, in which participants will receive 6 hours of one-on-one simulation training augmented with expert feedback and interlaced with 4 hours of small group teaching on the theory of colonoscopy; or (2) the Gamified Curriculum Group, in which participants will receive the same curriculum with integration of the following game-design elements: a leaderboard summarizing participant performance, game narrative, achievement badges, and rewards for top performance. In line with a progressive learning approach, simulation training for participants will progress from low to high complexity simulators, starting with a bench top model and then moving to the EndoVR® virtual reality simulator. Performance will be assessed at three points: pre-training, immediately post-training and 4-6 weeks after training. Assessments will take place on the simulator at all three time points and transfer of skills will be assessed during two clinical colonoscopies 4-6 weeks post-training. Mixed factorial ANOVAs will be used to determine if there is a performance difference between the two groups during simulated and clinical assessments.

Ethics and dissemination: Ethical approval was obtained at St. Michael's Hospital. Results of this trial will be submitted for presentation at academic meetings and for publication in a peer-reviewed journal.

Strengths and limitations of this study

- The intervention in this randomized trial is a comprehensive gamified simulation-based curriculum in gastrointestinal endoscopy that includes a game narrative, performance tracking measures, and rewards. These game-design elements are grounded in educational theory.
- The primary outcome is clinical performance of live colonoscopies on real patients, which will be assessed by two blinded independent expert endoscopists using an assessment tool with strong validity evidence.
- Participants will be assessed immediately after training for skill acquisition, and 4-6 weeks after training to evaluate skill retention and transfer of skills to the clinical environment.
- There are significant human resources required for implementation with respect to tracking participants' game metrics and adjusting leaderboards.

Key Words: simulation; colonoscopy; gamification; skill acquisition

Introduction

Simulation-based training (SBT) provides a safe and effective means to enhance skills development in gastrointestinal endoscopy.[1,2] SBT is more effective when embedded within a curriculum that is grounded in educational theory.[3–6] While previous studies have demonstrated the effectiveness of comprehensive structured curricula and curricula based on a progressive learning approach[4,7], other instructional strategies may further enhance procedural skills training.

One such enhancement may lie in gamification. Gamification refers to the application of game design elements, (conceptual building blocks central to creating successful games) to traditionally non-game contexts.[8–10] The overall purpose of gamification is to "encourage behavioral change and promote desired attitudes."[11] Gamification has previously been applied in health-related settings such as health promotion and e-health.[12–14] More recently, it has been gaining traction in the medical education setting, as gamification has the potential to improve learning and learner attention, engagement, motivation and behaviour change.[8,15] In a recent randomized trial, participants were ranked on a leaderboard as they completed cardiopulmonary resuscitation (CPR) training.[16] After training, participants who were ranked on a leaderboard had significantly better technical skills acquisition on the CPR training device. Another recent trial evaluated the effect of competition on novices' ability to learn simulated laparoscopic cholecystectomy.[17] The authors found that participants who engaged in competition demonstrated fewer movements and a shorter path length, suggesting increased efficiency.

While these reports highlight the potential benefits of gamification in educational contexts, the use of leaderboards and competition represent narrow applications of gamification. To date, there are no studies that have investigated the application of a comprehensive gamified curriculum that integrates multiple game design elements for procedural learning in medicine. Additionally, no studies have reported clinical outcomes on real patients. To bridge these gaps, we aim to determine the impact of a gamified simulation-based curriculum in endoscopy on clinical performance, compared to an identical curriculum that does not incorporate game design elements.

Methods & Analysis

Study Design

This single-blinded, parallel group, randomized controlled trial (RCT) is currently being conducted at St. Michael's Hospital in Toronto, Canada. Recruitment started June 2017. The methodology was adapted from previous studies by our group.[3,4,18] We used the SPIRIT checklist when writing our report.[19] The study design is summarized below in **Figure 1**.

Participants

Thirty-six novice endoscopists (performed < 25 previous real and/or simulated colonoscopies) will be recruited by one author (MAS). Participants will be included if they are from the general surgery or gastroenterology residency programs at the University of Toronto. Participants will be excluded if they have performed greater than 25 previous real and/or simulated colonoscopies.

Simulators

Bench Top Simulator

The bench top colonoscopy simulator is comprised of a series of vertical wooden barriers with numbered holes conforming to 27 different sequences of varying complexity. Participants use a real videocolonoscope, which provides visual output, to navigate through each sequence. This bench top endoscopy simulator helps develop general endoscopic skills and has shown good validity evidence for training novices.[20]

Virtual Reality Simulator

The EndoVR® virtual reality (VR) endoscopy simulator (CAE Healthcare, Montreal) is used for the VR training and all simulator tests. It models navigation through a colon, using a specialized endoscope that is inserted into a computer-based module with a screen showing

the colonic lumen of a virtual patient. It provides visual and haptic feedback related to the procedure. The simulator has several standardized case-based scenarios of varying complexity for colonoscopy and has robust validity evidence in the context of novices.[21,22]

Experimental Design

(1) Baseline questionnaires

Participants will complete a questionnaire to collect baseline demographic information, including age, sex, level of training, and previous endoscopic experience. Questions regarding experience with team sports and video games will also be included, as these may correlate with baseline endoscopic skil[23] (**Appendix 1**). Additionally, scales assessing the following variables will be administered: (1) competitiveness (Revised Competitiveness Index, **Appendix 2**); (2) self-efficacy (adapted General Self-Efficacy Scale, **Appendix 3**); and (3) game-type personality (Gamified User Personality Hexad, **Appendix 4**). All the included scales have good validity evidence.[24–26]

(2) Pre-test

Participants will complete a series of assessments prior to training to assess (1) their baseline knowledge of colonoscopy (knowledge test); (2) technical skills (VR simulation test); and (3) non-technical skills (VR simulation "integrated scenario" test). No feedback will be provided at any point during these assessments.

1. *Knowledge Test:* A 30-minute, 17 item multiple choice question (MCQ) test designed to assess core concepts related to colonoscopy, including indications, pathology, and theory underpinning non-technical skills (**Appendix 5**).
2. *VR Simulation Test:* A colonoscopy procedure on the VR simulator with a time limit of 30 minutes. Baseline technical proficiency will be assessed by an expert endoscopist. The procedure will be video-recorded, with identifying features hidden, to allow for a blinded assessment at a later time.[27]
3. *VR Simulation "Integrated Scenario" Test:* A test in which participants will complete a colonoscopy procedure on the VR simulator in a naturalistic setting (i.e., endoscopy suite) while interacting with a standardized nurse and standardized patient.[28] Trainees will be expected to take a brief patient history and obtain informed consent. The trainee will then carry out the procedure (EndoVR® Module 3 - Polypectomy) as described above while responding to the patient and interacting with the nurse as appropriate. As in the technical test, performance will be assessed in real time and videotaped, ensuring anonymity is preserved.

(3) Training intervention

Following the pre-tests, participants will be randomized to one of two training groups, following a 1:1 allocation distribution
with no stratification. One author (RK) used an online sequence generator (https://www.random.org/sequences/) to generate a random sequence of numbers and placed labels with these numbers into sealed envelopes. Another author (MP), not involved in sequence generation, distributed the sealed envelopes to participants as they arrived for the course. The first author (RK) was not present during envelope distribution. Investigators were blinded to group allocation.

1. *Conventional Curriculum (controls)***:** The control group will receive a total of four, one-hour, small-group teaching sessions covering the theory of colonoscopy, including pathology, anatomy, and therapeutic technique. One session is dedicated to non-technical skills relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. In this session, participants will watch a video demonstrating ideal endoscopic non-technical skills and learn about the Endoscopic Non-Technical Skills (E-NTS) checklist which will be provided for them to use during the integrated scenario training (**Appendix 6**). This checklist was developed in accordance with evidence-based recommendations, and outlines key endoscopic non-technical skills.[29] Following each teaching session, a short MCQ test on the topics covered in that session will be administered, in keeping with the "test-enhanced learning" literature.[30] In addition to teaching sessions, the control group will be given a total of six hours of expert-assisted instruction on both the bench top simulator (1 hour) and the VR simulator (5 hours).

Six modules of increasing difficulty in colonoscopy will be taught with one-on-one feedback from an expert academic endoscopist. The instructor will demonstrate techniques, answer questions and provide individualized performance feedback with a focus on non-technical skills. The last two hours of training on the VR simulator will consist of integrated scenarios, which feature a standardized patient and nurse. Following each scenario, the instructor will debrief the trainee on their performance, using the "E-NTS Checklist" as a framework for discussing their non-technical skills.

2. *Gamified Curriculum (GC):* This group will receive the same 4 hours of small group teaching and 6-hours of hands-on simulator training. Within the context of the teaching sessions and simulator training, the gamified curriculum will incorporate the following game design elements: a game narrative; performance tracking measures; and rewards. First, a game narrative will underlie the delivery of the gamified curriculum. Participants will be assigned an avatar and will be tasked with completing a journey of the avatar around a game-board shaped like the colon (**Appendix 7**) with the goal of reaching the final destination, the terminal ileum. Second, performance tracking measures will be used to allow participants to gauge their performance over time. These measures will be summarized on a leaderboard, which will include 4 components: a non-technical skills score; a technical skills score; a cognitive skills score; and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the Modified Objective Structured Assessment of Non-Technical Skills (MOSANTS) (**Appendix 8**) and the Joint Advisory Group for Gastrointestinal Endoscopy's Direct Observation of Procedural Skills (JAG DOPS) tool (**Appendix 9**), respectively. Scoring of cognitive skills will be based on MCQ test scores from the teaching sessions. Scores will be aggregated on the leaderboard for participants training on the same days. The leaderboard will be presented to participants after they finish each hour of practice. Finally, participants will engage in a system of both short-term and long-term rewards. One short-term reward will involve badges to recognize achievements of procedural benchmarks (e.g. cecal intubation) (**Appendix 10**). Another short-term reward will be the assignment of a wearable medallion, which will be given to the participant with the highest overall ranking at the end of each hour of practice. The long-term reward will be a low-cost prize (i.e. less than $25 CAD) given to the participant with the highest overall ranking throughout practice. All three game design elements (game narrative, performance tracking measures, reward system) will be introduced to participants in the gamified curriculum group prior to training with a brief tutorial video. After watching the video, participants will receive an anonymized ID to allow for self-tracking on the leaderboard while keeping individual scores private.

   All three game design elements are consistent with recommendations from the gamification and educational literature. In line with self-determination theory, leaderboards are purported to increase users' sense of relatedness, engagement and competence through social comparison, feedback provision and documentation of achievement.[31] The rationale for achievement badges and other rewards is that they serve as visual symbol of attained goals, thus supporting participants' sense of competence and serving to foster external motivation and engagement[31,32]. Finally, game narratives are thought to enhance engagement through the integration of meaning and interaction.[9] These elements must be carefully calibrated to challenge and engage learners appropriately and to ensure maintenance of learners' intrinsic motivation.[8,15]

(4) Post-test

Participants will complete a series of assessments immediately after training (immediate post-test). These will assess: (1) knowledge acquisition; (2) technical skills acquisition; and (3) non-technical skills acquisition. They will include the same *Knowledge Test*, *VR Simulation Test*, and *VR Simulation "Integrated Scenario" Test* that participants will complete during the *Pre-test.*

(5) Delayed testing (Retention and Transfer)

Participants will complete a series of assessments 4 to 6 weeks after training to assess their retention and transfer of skills. These will assess the following: (1) knowledge retention; (2) technical skills retention; (3) non-technical skills retention; and (4) transfer of skills to the

clinical environment. They will include the same *Knowledge Test*, *VR Simulation Test*, and *VR Simulation "Integrated Scenario" Test* that participants will complete during the *Pre-test* and the *Post-test*. To assess for transfer of skills to the clinical environment, participants will also complete two live colonoscopies on real patients. . These two procedures occurred simultaneously on a single day between 4 and 6 weeks after completion of training .These procedures will be videotaped in a manner that anonymizes the identity of the participant and the patient. Procedures on patients with a history of colonic or pelvic surgery or difficult colonoscopy will be excluded. Sedation and monitoring will be carried out according to standard practices on the endoscopy unit. An experienced attending endoscopist (completed > 500 previous colonoscopies) will provide verbal and/or hands-on assistance as necessary and take over if the participant cannot complete the procedure, or if any concerns regarding patient safety ariose. All patients were consented for the use of their procedure in this study.

Patient and Public Involvement

We based our approach to patient involvement on previously published studies focusing on clinical outcomes for endoscopic training[3,4], Specifically, patient involvement will be limited to their participation in the primary outcome, which involves assessment of clinical colonoscopies by study participants. Patients will not be required to evaluate the impact of the intervention. There will be no public involvement.

Primary outcome measure

The primary outcome measure is clinical performance during two live colonoscopies 4 to 6 weeks after training, as assessed by the JAG DOPS.[33]. Each clinical colonoscopy will be independently assessed by two experienced endoscopists who will be blinded to group assignment. One rater will be present during the procedure and the other rater will assess the participant's performance using the video-recorded procedure. Video-based assessment of endoscopic performances has been shown to have good validity evidence, compared to live assessment.[27]

Secondary outcome measures

1. Knowledge acquisition, as assessed by the MCQ Knowledge Tests
2. Technical skills acquisition during the VR Simulation Tests, as assessed by the JAG DOPS (**Appendix 9)**
3. Non-technical skills acquisition during the Integrated Scenario Test, as assessed by the Modified Objective Structured Assessment of Non-Technical Skills (M-OSANTS) for colonoscopy, which has good validity evidence for surgery and was modified for endoscopy[5] (**Appendix 8)**
4. Patient comfort during the clinical colonoscopies, as assessed by the endoscopy nurses using the Nurse-Assessed Patient Comfort Score (NAPCOMS)[34] **(Appendix 11**)

Exploratory outcome measures

5. Participant self-efficacy after each simulated and clinical colonoscopy testing procedure, as measured by an adapted General Self-Efficacy Scale[25] (**Appendix 3**)
6. Cognitive load after each simulated and clinical colonoscopy testing procedure, as measured by the Cognitive Load Scale for Colonoscopy[35] (**Appendix 12**)
7. Participant competitiveness after each simulated and clinical colonoscopy testing procedure, measured using the Revised Competitiveness Index[24] (**Appendix 2**).

Experienced endoscopists will assess participants' technical skills and non-technical skills during the pre-training, immediate and delayed post-training simulation-based assessments.

Data Management

Data will be collected through paper forms directly from assessors. Data from the forms will be extracted and input into a database on a password-protected computer. There is no requirement for a data monitoring committee as this is not a trial addressing the efficacy of a treatment nor is patient safety at risk. Details with respect to protection of confidentiality of participant data is outlined in the participant and patient consent forms (**Appendix 13,**

Appendix 14).

Analysis Plan
Statistical analyses will be performed using SPSS version 20 (SPSS, Inc, Chicago, IL). Alpha for all statistical tests will be set at 0.05. For all primary and sub-group analysis, appropriate measures will be taken to minimize an inflated Type I error due to multiple comparisons.

Baseline Questionnaire: Participant baseline variables will be characterized with descriptive statistics, using mean with standard deviation for continuous variables and number frequency for categorical variables, respectively.

Clinical Performance: Performance during the live colonoscopies will be compared between the two groups using the JAG DOPS, NAPCOMS, and MOSANTS scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (procedure 1 vs. procedure 2) analysis of variance (ANOVA) will be used. ANOVA differences significant at $P < 0.05$ will be further analyzed using Tukey honestly significant difference (HSD) post hoc tests. In addition, sensitivity analyses of the mixed factor ANOVA will be performed with gender and residency program (i.e. gastroenterology, general surgery) as covariates, as previous literature has identified gender differences in the acquisition of surgical skills[36].

Technical Performance*:* Differences in technical skills acquisition on the simulator will be determined by comparing JAG DOPS scores between groups. Specifically, a mixed factor 2 (Gamified vs. Conventional Curriculum) x 3 (pre-test, post-test, retention test) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Non-Technical Skill Performance: Differences in non-technical skills acquisition on the simulator will be determined by comparing MOSANTS scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 3 (pre-test, post-test, retention test) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Competitiveness: Baseline competitiveness, as measured by the Revised Competitiveness Index and the Gamification User Types Hexad, will be compared between groups using an independent t-test for each index.

Self-efficacy: Differences in self-efficacy between groups will be determined by comparing General Self-Efficacy Scale scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (pre-course vs. post- course) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Cognitive Load: Differences in cognitive load between groups will be determined by comparing Cognitive Load Index of Colonoscopy scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (pre-course vs. post- course) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Sample size estimation
Since there are no prior studies investigating a gamified curriculum for procedural learning, we conducted the power analysis based on the effect size from a previous study that evaluated an SBT curriculum for endoscopy.[3] Based on an effect size of 1.0 (Cohen's d), an alpha of 0.05 (two-tailed), a beta of 0.10, 2 groups, and 2 measurements, a minimum of 17 participants will be required to achieve a power of greater than 0.90 using repeated measures ANOVA (between-factors). To accommodate for a potential 5% dropout and/or non-response, we will recruit a total of 36 participants.

Ethics and Dissemination
Research ethics approval was granted by the St. Michael's Hospital Research Ethics Board (17-092). Protocol version 1.0, dated March 23, 2017, was approved. If any protocol modifications are needed, they will be made after communication with the research ethics board and will be detailed in any subsequent publications. Informed consent will be obtained from endoscopist participants and patients on whom participants will perform colonoscopies by one author (MAS). No personal health data on patients will be collected. All authors will have access to trial data. We will disseminate the results of the study through peer-reviewed

publication in journals and at scientific meetings. We do not plan to make participant-level data publicly available. The trial is registered at clinicaltrials.gov NCT03176251

Feasibility

To date, 21 participants have been recruited, randomized and have completed the study. Data collection is ongoing and is intended to reach completion by August 2018. Subsequent data analysis, manuscript writing and submission for publication are anticipated to reach completion by July 2019.

Discussion

The use of SBT for procedural skills training is widespread. In the report commissioned by the Future of Medical Education in Canada Postgraduate Project, the authors conclude that "simulation… needs to be integrated more thoughtfully into postgraduate curricula."[37] We aim to respond to this call through the development of an SBT curriculum grounded in educational theory. The strengths of this study lie in its randomized design and incorporation of various game design elements into the curriculum. Additionally, the primary outcome is measured in the clinical setting by two blinded expert assessors using an assessment tool with strong validity evidence. Finally, participants will be assessed both immediately after training for skill acquisition, and 4-6 weeks after training to evaluate skill retention and skill transfer to the clinical environment. There are several limitations of this study, which includethe significant human resources required to track participants' game metrics and adjust leaderboards, the identification of participants who have the wearable medallion, used to signify the participant in the study arm with the highest ranking after each hour of practice, and that participant frustration with underperforming was not included as a measure.

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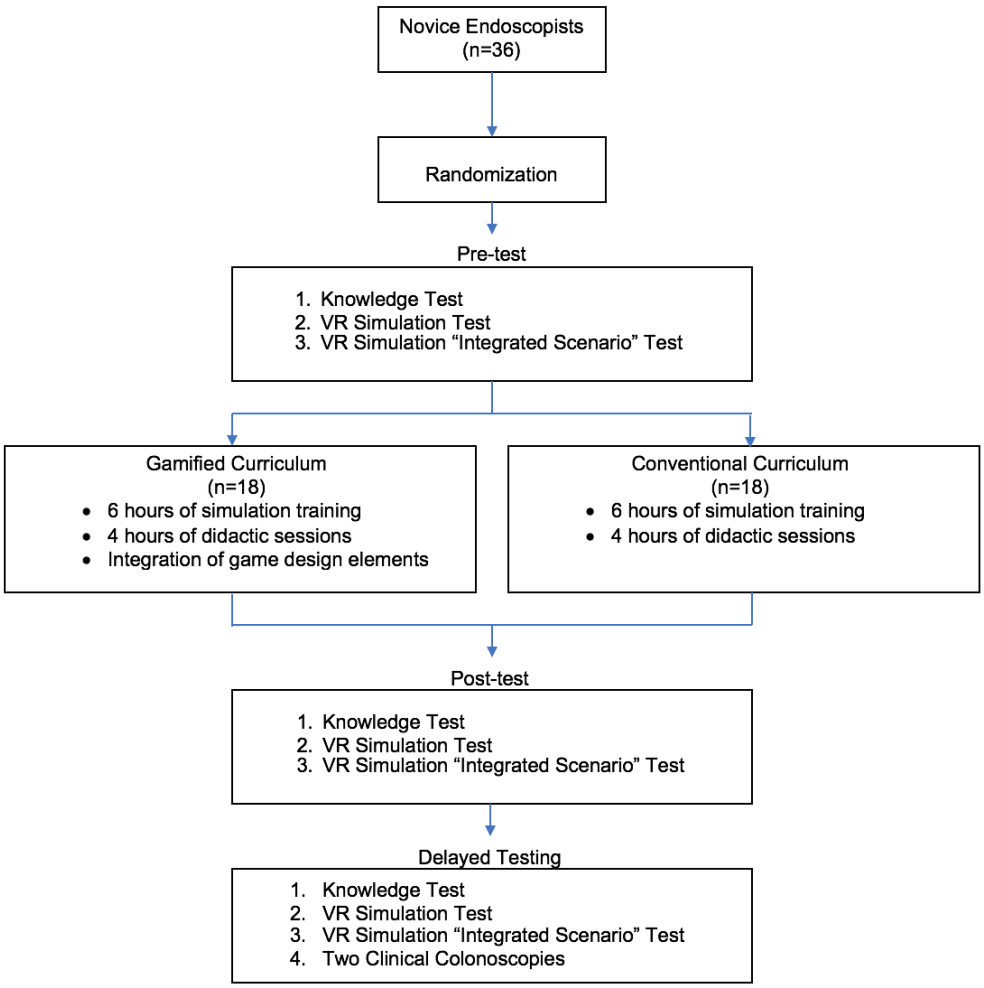
FIGURES

Figure 1: Study design.



Study design

195x198mm (144 x 144 DPI)

APPENDIX I:

BASELINE QUESTIONNAIRE

Participant ID Number: _____

1) Sex: □ Female □ Male

2) Age: _____

3) Handedness: □ Right □ Left □ Ambidextrous

4) Year of graduation from Medical School: _____

5) Programme:

□ Adult Gastroenterology
□ Pediatric Gastroenterology
□ General Surgery
□ Other (please specify: _____)

6) Level of training:

□ PGY 1
□ PGY 2
□ PGY 3
□ PGY 4
□ PGY 5
□ Other (please specify: _____)

7) Do you have previous experience in playing video games? □ Yes □ No

If yes, please specify:

(a) How many hours do you play on average per week? _____

(b) What types of games do you play? □ Sports □ Role-playing □ Real-time strategy □ Other (please describe)

8) Do you have previous experience in performing gastrointestinal endoscopy in the clinical or simulated setting? □ Yes □ No

If yes, please specify:

(c) Number of previous upper endoscopies in the ***clinical*** setting (attempted or completed): _____

(d) Number of previous upper endoscopies in the ***simulated*** setting (attempted or completed): _____

(e) Number of previous colonoscopies in the ***clinical*** setting (attempted or completed): _____

(f) Number of previous colonoscopies in the ***simulated*** setting (attempted or completed): _____

(g) Number of previous sigmoidoscopies in the ***clinical*** setting (attempted or completed): _____

(h) Number of previous sigmoidoscopies in the ***simulated*** setting (attempted or completed): _____

(i) Number of other ***clinical*** GI endoscopy procedures (please specify procedure): _____

_____
_____

(j) Number of other ***simulated*** GI endoscopy procedures (please specify procedure): _____
_____
_____

Competitiveness Scale

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
I like competition	1	2	3	4	5
I am a competitive individual	1	2	3	4	5
I enjoy competing against an opponent	1	2	3	4	5
I don't like competing against others	1	2	3	4	5
I get satisfaction from competing with others	1	2	3	4	5
I find competitive situations unpleasant	1	2	3	4	5
I dread competing against others	1	2	3	4	5
I try to avoid competing with others	1	2	3	4	5
I often try to outperform others	1	2	3	4	5
I try to avoid arguments	1	2	3	4	5
I will do almost anything to avoid an argument	1	2	3	4	5
I often remain quiet rather than risk hurting another person	1	2	3	4	5
I don't enjoy challenging others even when I think they are wrong	1	2	3	4	5
In general, I will go along with the group rather than create conflict	1	2	3	4	5

The General Self-Efficacy Scale

Please rate the following items based on a 4-rank scale.

1= Not at all true 2= Hardly true 3= Moderately true 4= Exactly true

	RATING
I can always manage to solve difficult problems if I try hard enough.	
If someone opposes me, I can find the means and ways to get what I want.	
It is easy for me to stick to my aims and accomplish my goals.	
I am confident that I could deal efficiently with unexpected events.	
Thanks to my resourcefulness, I know how to handle unforeseen situations.	
I can solve most problems if I invest the necessary effort.	
I can remain calm when facing difficulties because I can rely on my coping abilities.	
When I am confronted with a problem, I can usually find several solutions.	
If I am in trouble, I can usually think of a solution.	
I can usually handle whatever comes my way.	

Gamification User Types Hexad Personal Questionnaire

	Strongly Agree	Agree	More or less agree	Undecided	More or less disagree	Disagree	Strongly disagree
It makes me happy if I am able to help others	1	2	3	4	5	6	7
I like helping others to orient themselves in new situations	1	2	3	4	5	6	7
I like sharing my knowledge	1	2	3	4	5	6	7
The wellbeing of others is important to me	1	2	3	4	5	6	7
Interacting with others is important to me	1	2	3	4	5	6	7
I like being part of a team	1	2	3	4	5	6	7
It is important to me to feel like I am part of a community	1	2	3	4	5	6	7
I enjoy group activities	1	2	3	4	5	6	7
It is important to me to follow my own path	1	2	3	4	5	6	7
I often let my curiosity guide me	1	2	3	4	5	6	7
I like to try new things	1	2	3	4	5	6	7
Being independent is important to me	1	2	3	4	5	6	7
I like defeating obstacles	1	2	3	4	5	6	7
It is important to me to always	1	2	3	4	5	6	7

carry out my tasks completely							
It is difficult for me to let go of a problem before I have found a solution	1	2	3	4	5	6	7
I like mastering difficult tasks	1	2	3	4	5	6	7

I like to provoke	1	2	3	4	5	6	7
I like to question the status quo	1	2	3	4	5	6	7
I see myself as a rebel	1	2	3	4	5	6	7
I dislike following rules	1	2	3	4	5	6	7

I like competitions where a prize can be won	1	2	3	4	5	6	7
Rewards are a great way to motivate me	1	2	3	4	5	6	7
If the reward is sufficient I will put in effort	1	2	3	4	5	6	7
Return of investment is important to me	1	2	3	4	5	6	7

Endoscopy Knowledge Post-Test

This is the knowledge test for the University of Toronto endoscopic simulation course. Please type in your "endo" number to begin the test. The test consists of 17 questions for a total of 20 points.

The knowledge questions are on the next two pages. You have 30 minutes to answer these questions.

These answers are confidential, and your responses and score are only for the purposes of our research studies. They will not be used as part of your residency training assessments, or as part of competency assessments.

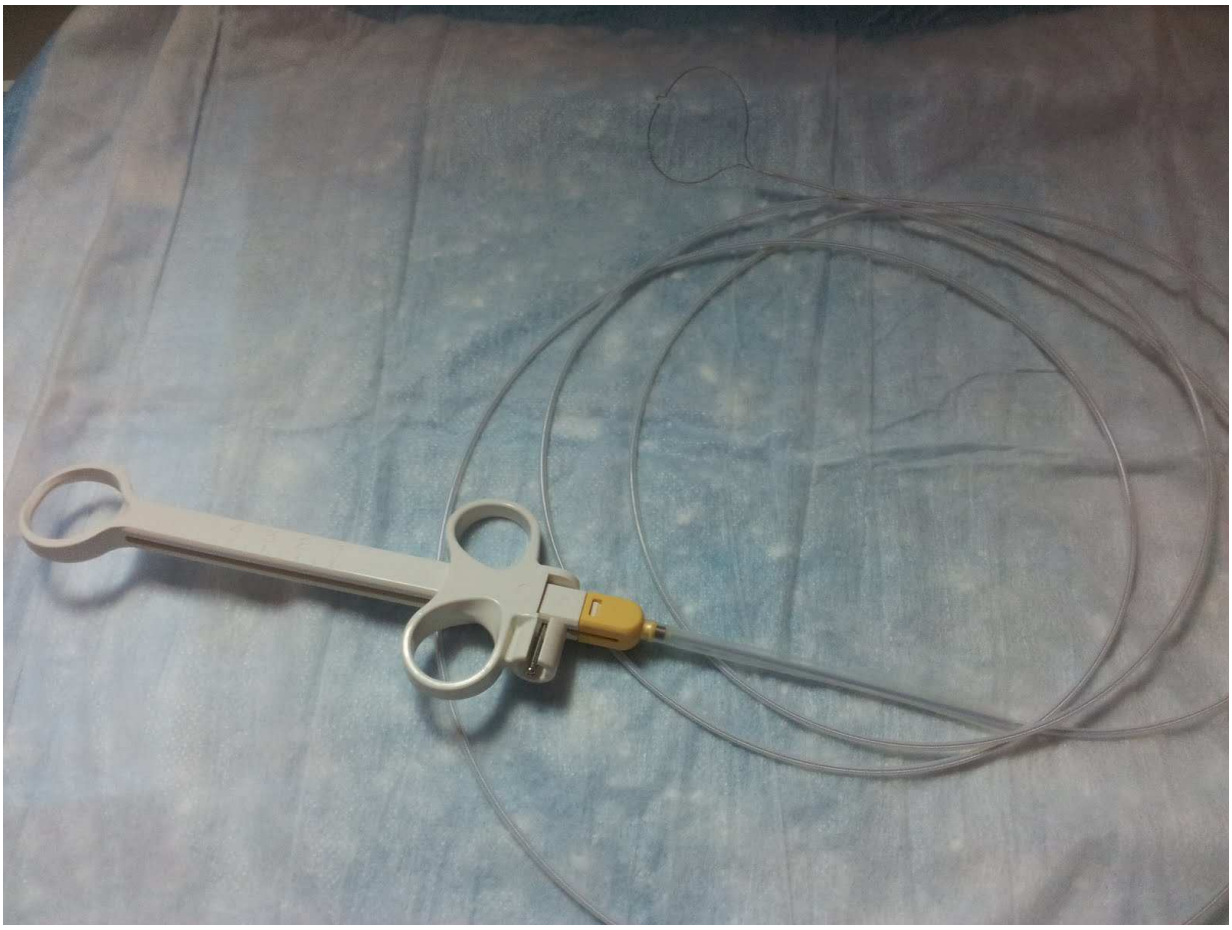
*Required

1. **Please type in your "endo" number login to start** *
   ie, "Endo10"

Endoscopic Knowledge Test (page 1 of 2)

2. **Question 1 (1 point)**
   Name the endoscopic device depicted below.
   Mark only one oval.

   - A. Endoloop
   - B. Endoscopic snare
   - C. Endoscopic biopsy forceps
   - D. Gold probe
   - E. Oval probe



3. **Question 2 (1 point)**

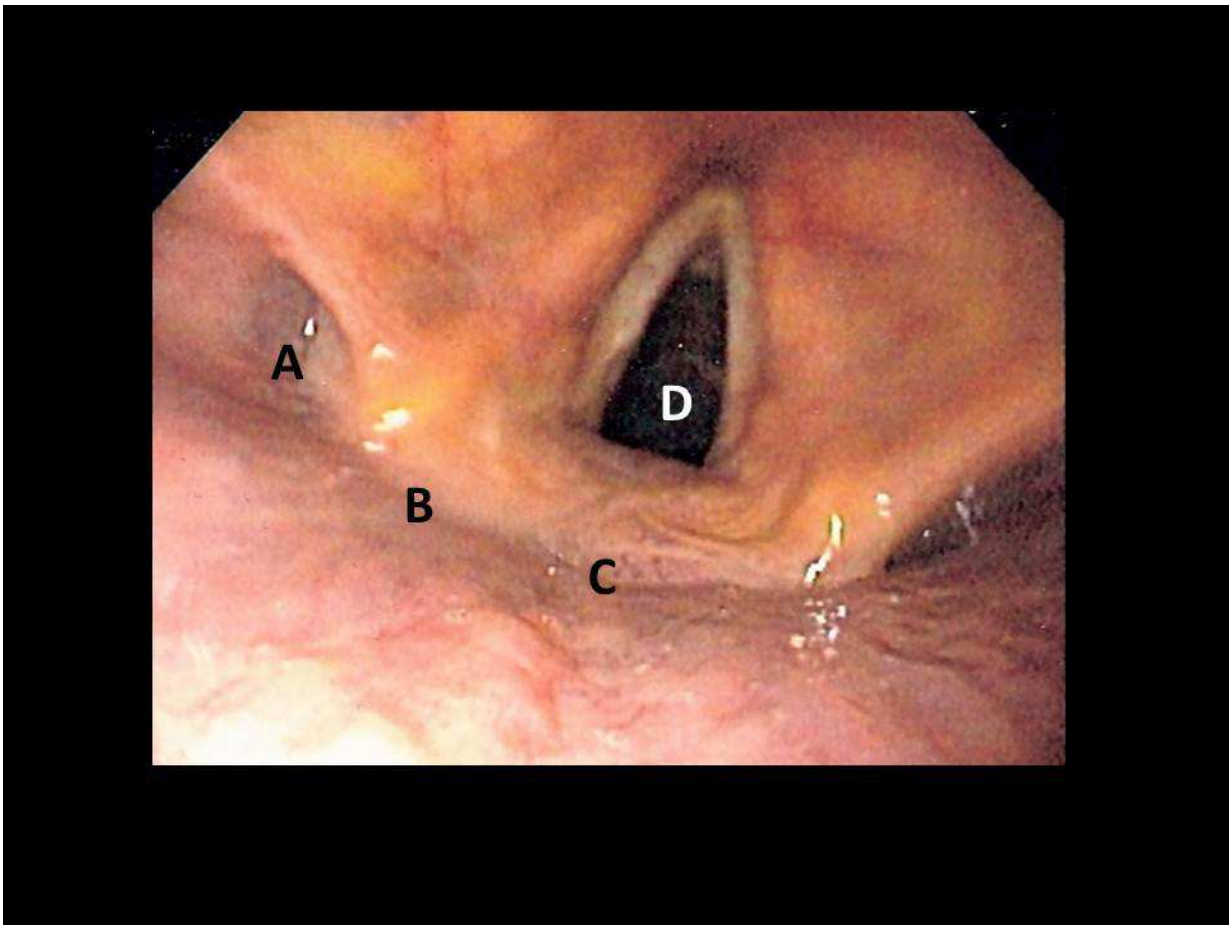
What type of sigmoid colon loop is most beneficial for entry into the descending colon?
Mark only one oval.

- A. Alpha-loop
- B. Reverse alpha-loop
- C. Gamma-loop
- D. N-loop
- E. Reverse-N loop

4. **Question 3 (1 point)**

Below is an endoscopic image of the larynx taken with a gastroscope. Which location is representative of the ideal place to position the gastroscope to intubate the esophagus?
Mark only one oval.

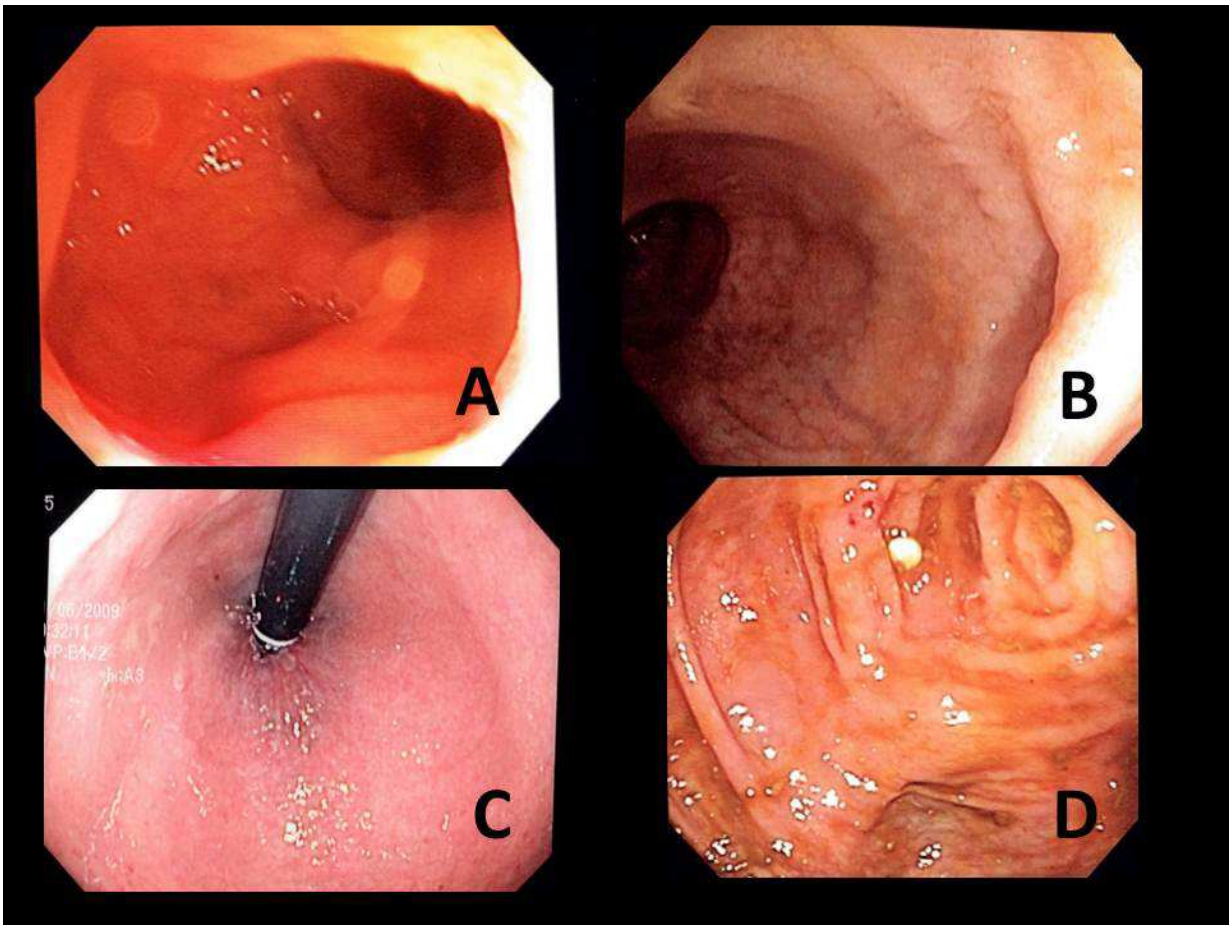
- A
- B
- C
- D



5. **Question 4 (1 point)**

Which of the images below is an endoscopic image of the cecum?
Mark only one oval.

- Image A
- Image B
- Image C
- Image D



6. **Question 5 (1 point)**

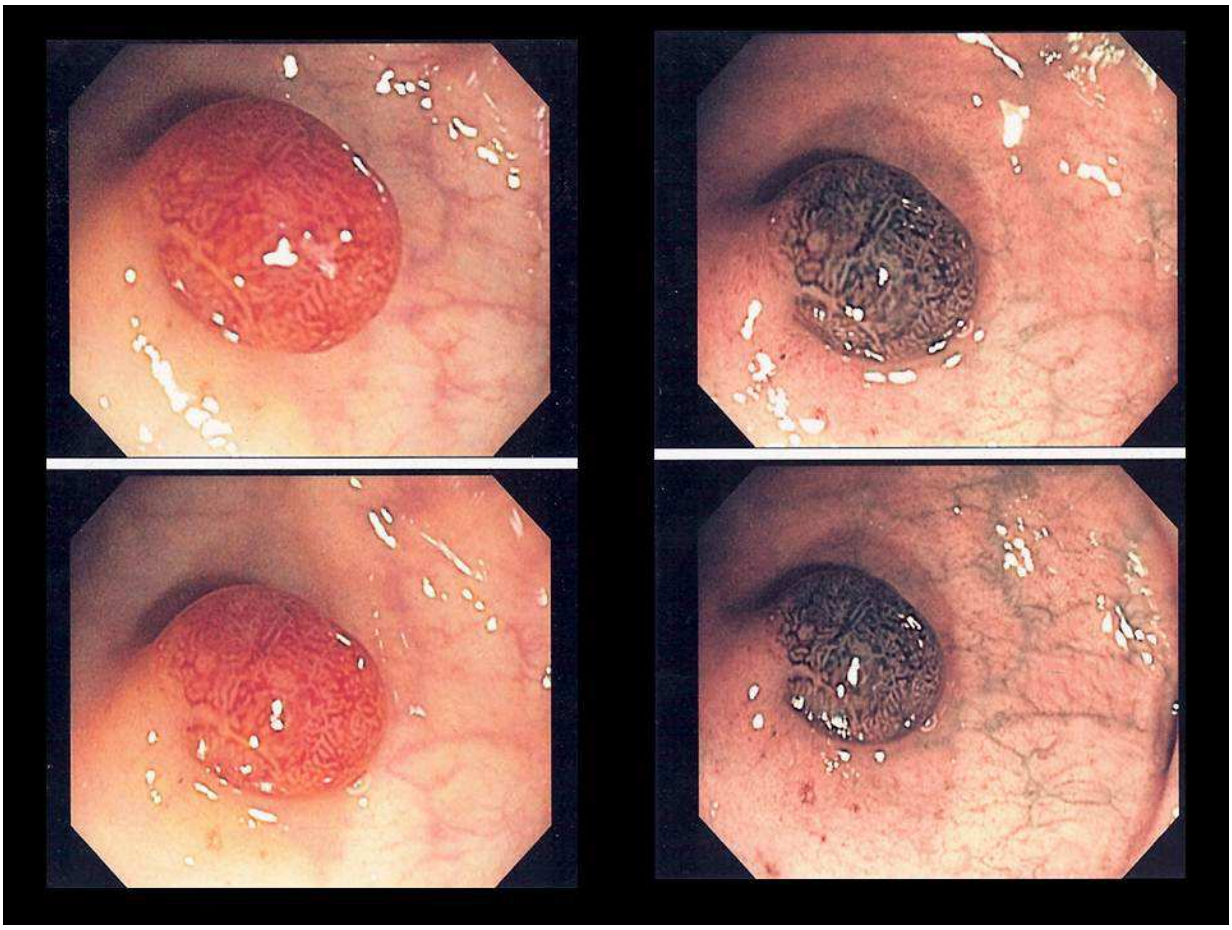
The pit pattern of polyps is commonly used as an endoscopic classification to determine the likely histopathology. What is the name of the classification most commonly used for pit patterns?
Mark only one oval.

- A. Kudo classification
- B. Maclean classification
- C. Yoshida classification
- D. Haggitt classification
- E. Sarin classification

7. **Question 6 (1 point)**

The pit patterns of the polyp depicted below have been enhanced by use of ambient light of blue-green wavelength (approximately 450 - 540 nm). What is the name of this technology?
Mark only one oval.

- A. Confocal microscopy
- B. Optical coherence tomography
- C. Chromoendoscopy
- D. FICE (Fuji intelligent chromoendoscopy)
- E. Narrow band imaging



8. **Question 7 (1 point)**

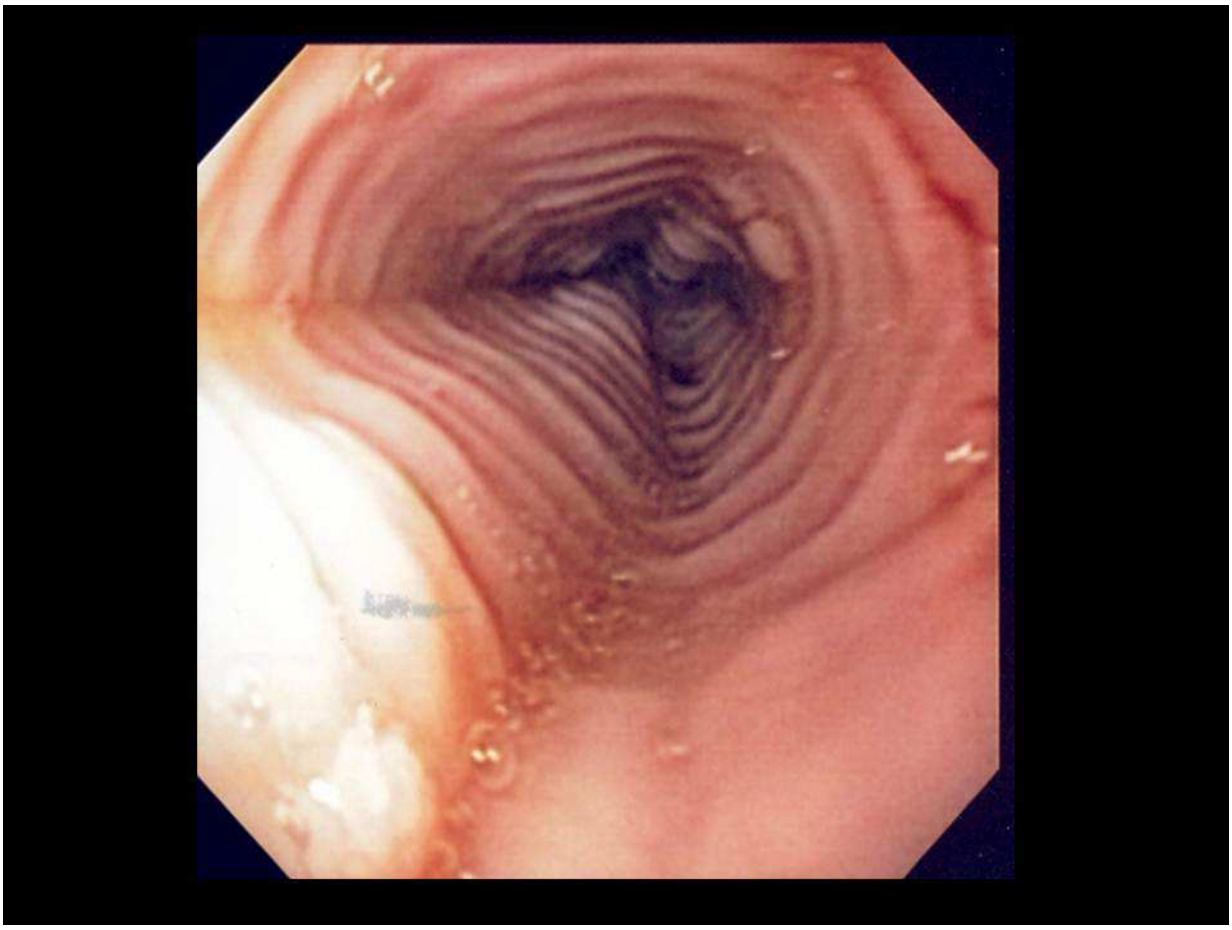
With a well prepared colonoscopy to the cecum performed by an experienced endoscopist, what is the approximate risk of missed advanced neoplasia?
Mark only one oval.

- A. 1%
- B. 3-5%
- C. 5-10%
- D. >10%

9. **Question 8 (1 point)**

Below is an endoscopic view of a patient's esophagus. What is the endoscopic diagnosis?
Mark only one oval.

- A. Eosinophilic esophagitis
- B. Radiation esophagitis
- C. Mosaic esophagus
- D. Barrett's esophagus
- E. Diffuse-type squamous cell carcinoma



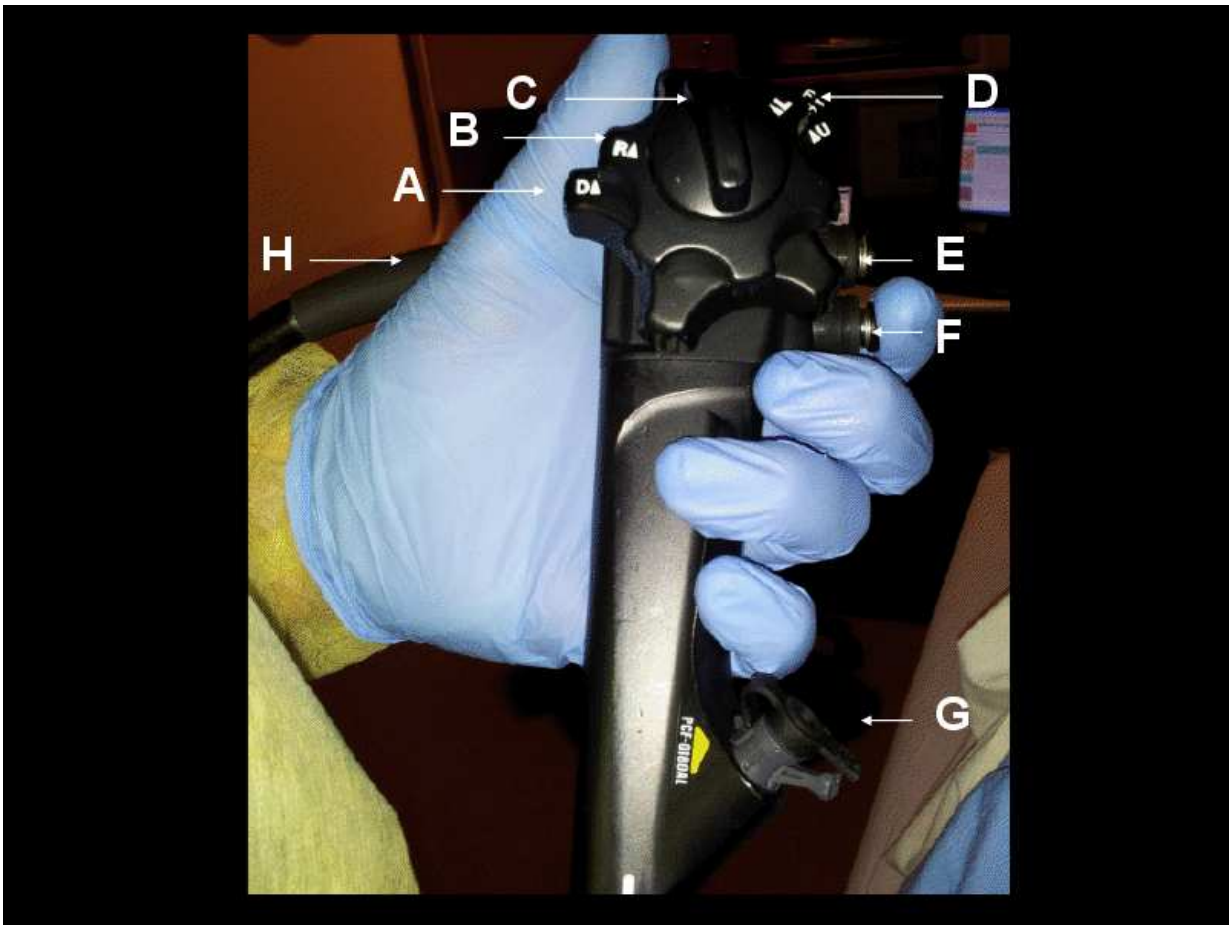
Endoscopy knowledge test (page 2 of 2)

10. **Question 9 (1 point)**

Which of the following is a commonly used bowel preparation score for colonoscopy?
Mark only one oval.

- A. Los Angeles bowel preparation score
- B. Ottawa bowel preparation score
- C. King's College bowel preparation score
- D. Chicago bowel preparation score
- E. Washington bowel preparation score

Question 10 (4 points)



Identify the labelled parts of the colonoscope head (4 points; 0.5 points each)

11. **A**

12. **B**

13. **C**

14. **D**

15. **E**

16. **F**

17. **G**

18. **H**

Question 11 (1 point)

Certain skills necessary for endoscopic performance may be independent of the technical performance of the procedure. Name four non-technical skills that you would view as important in the performance of endoscopic procedures.

19. **A**

20. **B**

21. **C**

22. **D**

23. **Question 12 (1 point)**

Which of the following is not a risk factor for colonic perforation at the time of colonoscopy
Mark only one oval.

- A. Barotrauma
- B. Mucosal injection
- C. Sigmoid looping
- D. Trainee endoscopist performing colonoscopy
- E. Resection of sessile polyp

24. **Question 13 (1 point)**

A 50 year old patient presents for a screening colonoscopy to your open access endoscopy unit. They have completed a 4L bowel preparation. Upon taking a history, you discover that they had a colonoscopy 2 years ago to work up anorectal bleeding but you don't have the results. What is the appropriate course of action?
Mark only one oval.

- A. Complete a screening colonoscopy because the indication of colorectal cancer screening is different than anorectal bleeding.
- B. Another screening colonoscopy is not needed; send patient home.
- C. Make concerted effort to track down report of prior colonoscopy and if not obtained, then proceed with screening colonoscopy.
- D. Make concerted effort to track down report of prior colonoscopy and if not obtained, then explain to patient that they can choose to defer procedure until report is obtained and reviewed
- E. Your endoscopic skills exceed that of the previous endoscopist and the procedure must be repeated.

25. **Question 14 (1 point)**

A unilingual Azerbaijani woman comes in for a gastroscopy to work up epigastric pain. She is unable to understand the consent process, which of the following is most correct?
Mark only one oval.

- A. Do a physical examination; if she has abdominal discomfort, continue with gastroscopy.
- B. Ask the patient's daughter to translate the consent form.
- C. Reschedule the gastroscopy and ask her to bring a translator.
- D. Reschedule the gastroscopy and arrange for a translator to accompany her.
- E. Obtain consent from daughter and proceed with procedure

26. **Question 15 (1 point)**

You are completing a screening colonoscopy and discover a 12 mm pedunculated polyp in the transverse colon. The endoscopy nurse suggests the use of a 10 mm snare and no electrocautery, but you believe a 15 mm snare with electrocautery would be more appropriate. What do you do?
Mark only one oval.

- A. Take the nurse's suggestion since he/she is more experienced than yourself.
- B. Use a 15 mm snare and ignore the nurse.
- C. Ask the nurse for the rationale for the smaller snare and the absence of cautery and verbalize your decision to proceed with the 15 mm snare with cautery.
- D. Discuss with the nurse why you wish to proceed with the larger snare and electrocautery before proceeding with the polypectomy.
- E. Call in a colleague to assist in the decision making.

27. **Question 16 (1 point)**

You are completing a polypectomy of a 2 cm Paris II-a (flat) polyp in the cecum of a 65 year old male. After the polypectomy you notice a perforation in the cecum. You aim to close the defect with endoclips, start antibiotics, and arrange imaging and possible surgery. Which of the following would not be appropriate?
Mark only one oval.

- A. Start the plan above for the management of the patient's complication, as soon as possible.
- B. Inform family members of the procedure's complications before proceeding with the above plan.
- C. Ensure airway, breathing and circulation are intact above all else.
- D. Call for extra assistance into the room as soon as possible.
- E. Stay calm as you manage the situation.

28. **Question 17 (1 point)**

You perform a screening colonoscopy on an anemic 50 year old male who complains of weight loss, altered bowel habits and blood in his stool. You identify the patient is suffering from colorectal cancer. Which one of the following would not be appropriate in explaining the results of the colonoscopy to the patient?
Mark only one oval.

- A. Ensure the results are delivered in a private setting
- B. Do not inform the patient of the suspected diagnosis until you have the pathology results
- C. Ensure to be empathetic during delivery of the results of the colonoscopy
- D. Establish that the patient understands the results after you explain it to them
- E. Be aware of the patient's reaction and tone as you are delivering the news

TEAMSTEPPS TEAMWORK ATTITUDES QUESTIONNAIRE

With respect to how each question applies to interactions with a team in ENDOSCOPY, please respond to the questions below by placing a checkmark in the box that corresponds to your level of agreement from Strongly Disagree to Strongly Agree. We realize that the questions may be a little vague but please select only one response for each question.

Team Structure

29. **1. It is important to ask patients and their families for feedback regarding patient care before/in/after endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

30. **2. Patients are a critical component of the care team in surgery and endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

31. **3. The Department of Surgery or Division of Gastroenterology influences the success of direct care teams in surgery and endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

32. **4. In surgery and endoscopy, the mission of the team is of greater value that the goals of individual team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

33. **5. Effective team members can anticipate the needs of other team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

34. **6. High-performing teams in health care share common characteristics with high-performing teams in other industries** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Leadership

35. **7. It is important for a surgeon-leader or GI-leader to share information with team members** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

36. **8. Leaders should create informal opportunities for team members to share information** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

37. **9. Effective leaders view honest mistakes as meaningful learning opportunities** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

38. **10. It is a leader's responsibility to model appropriate team behaviour** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

39. **11. It is important for surgeon-leaders or endoscopy-leaders to take time to discuss their team members' plans for each patient** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

40. **12. Team leaders should ensure that team members help each other out when necessary** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Situation monitoring

41. **13. Individuals can be taught how to scan the patient environment in the OR or procedure room for important situation cues.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

42. **14. Monitoring patients provides an important contribution to the effective performance of the team** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

43. **15. Even individuals who are not part of the direct care team should be encouraged to scan for and report changes in patient status** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

44. **16. It is important to monitor the emotional and physical status of other team members** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

45. **17. It is appropriate for one team member to offer assistance to another who may be too tired or stressed to perform a task** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

46. **18. Team members who monitor their emotional and physical status on the job are more effective** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Mutual support

47. **19. To be effective, team members should understand the work of their fellow team members.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

48. **20. Asking for assistance from a team member us a sign that that individual does not know how to do his/her job effectively** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

49. **21. Providing assistance to team members is a sign that an individual does not have enough work to do** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

50. **22. Offering to help a fellow team member with his/her individual work tasks is an effective tool for improving team performance** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

51. **23. It is appropriate to continue to assert a patient safety concern until you are certain that it has been heard.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

52. **24. Personal conflicts between team members do not affect patient safety** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Communication

53. **25. Teams that do not communicate effectively significantly increase their risk of committing errors** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

54. **26. Poor communication is the most common cause of reported errors** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

55. **27. Adverse events may be reduced by maintaining an information exchange with patients and their families** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

56. **28. I prefer to work with team members who ask questions about information I provide** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

57. **29. It is important to have a standardized method for sharing information when handing off patients after endoscopy** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

58. **30. It is nearly impossible to train individuals how to be better communicators** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

59. **Please indicate any additional comments in the space below.**

Thanks for your participation.

Powered by
Google Forms

Endoscopist Participant ID #: _____ Date (DD/MM/YYYY): _____ Start Time: _____

End Time: _____

Assessor: Self-Assessment VR Simulator (circle one): 1 2 3

VR Case: _____

ENDOSCOPIC NON-TECHNICAL SKILLS SELF-REFLECTION TOOL

	Y / N
1. Did I take a focused patient history?	
2. Did I review the patient's medications (i.e. anticoagulants) and allergies?	
3. Did I identify the correct procedure and take an appropriate consent?	
4. Did I discuss the sedation plan with the anesthetist or RN?	
5. Did I introduce the team and myself to the patient?	
6. Did I discuss the procedure with the patient and address concerns?	
7. Did I ask the team if they were ready to start?	
8. Did I situate the patient in the correct position?	
9. Did I verbalize/acknowledge relevant anatomy/landmarks?	
10. Did I check vital signs often (every few minutes)?	
11. Did I update the team and patient on the progress of the procedure?	
12. Did I address patient comfort (i.e. ask the patient where pain is) and enact a plan for a patient who was not comfortable?	
13. Did a secondary goal arise during the procedure (e.g. polypectomy)? Did I identify issues and problems that arose from this scenario? Did I verbalize the plan to attend to these?	
14. Did I use closed-loop communication when interacting with the team?	
15. Did I discuss results with the patient post-procedure (i.e. complication, what was found, etc.) and create a follow-up plan?	
16. Was I respectful toward the patient and team?	
17. Did I identify any errors I made afterward? If so what can I do to improve my performance?	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M-OSANTS – NON-TECHNICAL SKILLS

SITUATIONAL AWARENESS: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to remain aware of the patient's history (e.g. allergies, medications, etc.)? Did the endoscopist review procedural details prior to procedure (e.g. confirms correct procedure)? Did the endoscopist demonstrate procedural planning (e.g. identifies objectives for the procedure at the start)? Did the endoscopist collect and use information during the procedure (e.g. change in vital signs)? Did the endoscopist recognize the scope of practice (e.g. refrain from unfamiliar procedures/ interventions)? Did the endoscopist anticipate potential problems during the procedure while proposing suitable solutions (e.g. proactively apply loop reduction strategies)? Was the endoscopist mindful of procedure time? Did the endoscopist ensure that patient outcomes are met (e.g. maintain patient comfort)? Did the endoscopist anticipate needs of team members and of the patient (e.g. minimize patient anxiety)?				

DECISION MAKING: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to implement endoscopic and clinical knowledge when making a decision (e.g. choosing equipment appropriate to endoscopic appearance)? Did the endoscopist identify issues and subsequently tailor a plan for resolution (e.g. application of loop reduction strategies)? Did the endoscopist confidently create a plan and articulate details of the plan to the team)? Did the endoscopist demonstrate understanding of the risks and benefits of an intervention/ maneuver (e.g. aware of bleeding risk due to polypectomy)? Did the endoscopist account for relevant patient information (e.g. mindful of contraindications)? Did the endoscopist appropriately delegate tasks to staff (e.g. requesting equipment from nurses)? Did the endoscopist enact a subsequent option if initial action unsuccessful? Did the endoscopist respond appropriately if the procedure extends out of the endoscopist's scope of practice (e.g. asking for assistance from senior staff)?				

COMMUNICATION: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to receive and respond to information from team members? Did the endoscopist actively limit distractions in the room (e.g. restricts cell phone use)? Did the endoscopist convey information using a closed-loop (e.g. confirms amount of sedation to be administered)? Did the endoscopist speak with clarity, while providing details when appropriate (e.g. requesting snare with specific size)? Did the endoscopist indicate a specific team member if there are multiple staff (e.g. addresses nurse by name)? Did the endoscopist use language appropriate for the recipient (e.g. minimizes medical jargon for patients)? Was the endoscopist aware of verbal tone and volume (e.g. speaks to staff in a respectful, collegial manner that can be heard)? Did the endoscopist ensure that the recipient understands information (e.g. patient comprehends risks)? Did the endoscopist relay findings to patient, including any adverse events (e.g. follow-up during aftercare)?				

LEADERSHIP: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to take responsibility for the process of the procedure (e.g. acknowledge mistakes)? Did the endoscopist direct the flow of the team process, including an appropriate delegation of labour (e.g. requesting that nurses attend to patient discomfort)? Did the endoscopist demonstrate confidence when leading the team, even under pressure (e.g. maintains composure during a bleed)? Did the endoscopist lead the endoscopic pause?				

PROFESSIONALISM: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Did the endoscopist demonstrate a respectful and courteous attitude towards the patient and team members (e.g. introduces himself/herself to everyone in the room)? Did the endoscopist acknowledge mistakes during procedure? Did the endoscopist display empathy for the patient (e.g. responds to patient discomfort)? Did he endoscopist advocate on behalf of the patient? Did the endoscopist manage time appropriately (e.g. mindful of endoscopy unit time)? Did the endoscopist ensure follow-up and address patient concerns within appropriate environment (e.g. follow-up within office or dedicated clinical area)? Did the endoscopist refrain from inappropriate conversations (e.g. does not discuss other patients during a procedure)? Did the endoscopist ensure that the procedure adheres to best-practice guidelines (e.g. record quality metrics)?				

TEAMWORK: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to act effectively within the team of nurses, technicians, management, and other physicians? Did the endoscopist demonstrate respect for all members of the team (e.g. speaks in a collegial, respectful tone)? Was the endoscopist aware of the roles of all members of the endoscopic team? Did the endoscopist display willingness to assist others, if appropriate (e.g. when transferring a patient)? Did the endoscopist ask for advice from other team members? Did the endoscopist take into account feedback from other team members (e.g. listens to suggestions for equipment)?				

Endoscopist Participant ID #: _____ Date (DD/MM/YYYY): _____ Start Time: _____

End Time: _____

Assessor: _____ VR Simulator (circle one): 1 2 3

VR Case: Polypectomy Case 3

Maximal distance reached (check one):

- ☐ Rectum
- ☐ Sigmoid
- ☐ Descending Colon
- ☐ Splenic Flexure
- ☐ Hepatic Flexure
- ☐ Ascending Colon
- ☐ Cecum
- ☐ Terminal Ileum

DOPS – TECHNICAL SKILLS

Please write the appropriate score from the scale below

Scale:
4 Highly skilled performance
3 Competent & safe throughout procedure, no uncorrected errors
2 Some standards not yet met, aspects to be improved, some errors uncorrected
1 Accepted standards not yet met, frequent errors uncorrected

CRITERIA	SCORE
Assessment, consent, communication	
• Obtains informed consent using a structured approach ○ Satisfactory procedural information ○ Risk and complications explained ○ Co-morbidity ○ Sedation ○ Opportunity for questions	**1 2 3 4**
• Demonstrates respect for patient's views and dignity during the procedure	**1 2 3 4**
• Communicates clearly with patient, including outcome of procedure with appropriate management and follow up plan. Full endoscopy report.	**1 2 3 4**
Safety and sedation	
• Safe and secure IV access (or indicates need)	**1 2 3 4**
• Gives appropriate dose of analgesia and sedation and ensures adequate oxygenation and monitoring of patient (or indicates does, need for monitoring)	**1 2 3 4**
• Demonstrates good communication with the nursing staff, including dosages and vital signs	**1 2 3 4**
Endoscopic skills	
○ Checks endoscope function before intubation (or indicates need to check)	**1 2 3 4**
○ Performs/Indicates need for PR	**1 2 3 4**
• Maintains luminal view / inserts in luminal direction	**1 2 3 4**
• Demonstrates awareness of patient's consciousness and pain during the procedure and takes appropriate action	**1 2 3 4**
○ Uses torque steering and control knobs appropriately	**1 2 3 4**
○ Uses distension, suction and lens washing appropriately	**1 2 3 4**
• Recognizes and logically resolves loop formation	**1 2 3 4**
○ Uses position change and abdominal pressure to aid luminal views	**1 2 3 4**
○ Completes procedure in reasonable time	**1 2 3 4**
Diagnostic and therapeutic ability	
• Adequate mucosal visualization	**1 2 3 4**
• Recognizes caecal/desc. colon landmarks or incomplete examination	**1 2 3 4**
• Accurate identification and management of pathology	**1 2 3 4**
• Uses diathermy and therapeutic techniques appropriately and safely	**1 2 3 4** ☐ **N/A**
• Recognizes and manages complications appropriately	**1 2 3 4** ☐ **N/A**

Appendix X: Badge Table

Requirement Needed	Standardized Hints	Setting	Hour
Complete a case in less than a minute	Complete a case in less than a minute	Low fidelity	Hour 1
Complete Low Fidelity	Complete all Low fidelity cases	Low Fidelity	Hour 1
Proper Torque (as determined by assessor)	Torque properly	Low Fidelity	Hour 1
Less than 10% time in red-out	Be careful how much time in red out you spend.	Intro 3/4	Hour 2
Less than 90% Air left in colon	Remove an appropriate amount of air from the colon	Intro 3/4	Hour 2
Over 90% visualization	Make sure to have enough visualize the colon	Intro ¾	Hour 2
Identify the Ulcerative Colitis	ID a diagnosis	Intro 5	Hour 3
Identify pseudomembranous colitis	ID a diagnosis	Biopsy 3	Hour 3
Successful biopsy of Crohn's patient	Use the biopsy forceps	Poly 4	Hour 3 or 4
Take a Photo of a Pedunculated Polyp	Take photos	Poly 1	Hour 4
Identification of location of Polyp (splenic flexure or _cm in)	Say what you see	Poly 3	Hour 4
Outline major risks in colonoscopy Minimum of 4/5 1. Infection 2. Perforation 3. Missed lesions 4. Sedation complications 5. Bleeding	Pros and Cons	Integrated Scenarios	Hour 5/6
Pain acknowledgement (administration of meds, empathetic statement)	"Pain"	Integrated Scenarios	Hour 5/6

No time in extreme Pain	Patient comfort is important	Integrated Scenarios	Hour 5/6
Do an endoscopic Pause 1. Indicate a pause 2. Revise case 3. Feedback from SN	“Pause”	Integrated Scenarios	Hour 5/6
Retroflex without assistance	“Rectum”	High Fidelity	Any
Intubate the TI	Make sure you finish the whole pathway	High Fidelity	Any

Assessors please fill out

NURSE ASSESSED PATIENT COMFORT SCORE (NAPCOMS)

Domain	Item	0	1	2	3	Score
Pain	1- Intensity	None or minimal	Mild	Moderate	Severe	
	2- Frequency	None	Few (1 or 2 episodes)	Several times (3-4 episodes)	Frequent (>4 episodes)	
	3- Duration	None	Short duration (episode <30 seconds)	Moderate duration (30 sec-1 minute)	Long duration (episode lasts >1 min)	
	Total Pain Score (Intensity + Frequency + Duration)					
Sedation	Level of consciousness*	Alert	Sleepy but initiates conversation	Responds only when asked or stimulated	Unresponsive or only responds with pronounced simulation	
Global	Tolerability*	Very well tolerated	Reasonably well tolerated	Just tolerated	Poorly tolerated	

*Note: level of consciousness and tolerability are not used in overall score

Cognitive Load Index for Colonoscopy

CRITERIA	SCORE
Intrinsic load items: Please rate your agreement with the following statements regarding the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. Physically manipulating and controlling the colonoscope was difficult	**0 1 2 3 4 5 6 7 8 9 10**
2. Using ancillary instruments (i.e. biopsy forceps, polypectomy snare) was difficult	**0 1 2 3 4 5 6 7 8 9 10**
3. Identifying normal anatomy and/or landmarks was difficult	**0 1 2 3 4 5 6 7 8 9 10**
4. The endoscopic findings were complex or difficult to characterize	**0 1 2 3 4 5 6 7 8 9 10**
5. It was difficult to manage identified pathology (i.e. polyps that were difficult to remove, bleeding that was difficult to control)	**0 1 2 3 4 5 6 7 8 9 10**
6. It was difficult to keep track of, or remember, all the endoscopic findings	**0 1 2 3 4 5 6 7 8 9 10**
7. Managing the patient's level of comfort was difficult	**0 1 2 3 4 5 6 7 8 9 10**
8. Overall, this colonoscopy was difficult and/or complex	**0 1 2 3 4 5 6 7 8 9 10**
Extraneous load items: Please rate your agreement with the following statements regarding your experience during the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. My supervisor's instructions were unclear	**0 1 2 3 4 5 6 7 8 9 10**
2. My supervisor used language that was confusing or unfamiliar	**0 1 2 3 4 5 6 7 8 9 10**
3. The manner in which my superior provided instructions	**0 1 2 3 4 5 6 7 8 9 10**
4. I felt distracted by other people present in the endoscopy room	**0 1 2 3 4 5 6 7 8 9 10**
5. I felt distracted by the environment (i.e. my pager going off, environmental noise)	**0 1 2 3 4 5 6 7 8 9 10**
6. I felt distracted by things on my mind unrelated to this colonoscopy	**0 1 2 3 4 5 6 7 8 9 10**
Germane load items: Please rate your agreement with the following statements regarding your level of mental effort during the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. I invested substantial mental effort learning how to control or manipulate the colonoscope and/or other endoscopic equipment	**0 1 2 3 4 5 6 7 8 9 10**
2. I invested substantial mental effort identifying or understanding colonic anatomy	**0 1 2 3 4 5 6 7 8 9 10**
3. I invested substantial mental effort understanding, remembering and/or managing the endoscopic findings	**0 1 2 3 4 5 6 7 8 9 10**
4. I invested substantial mental effort learning how to manage patient comfort level	**0 1 2 3 4 5 6 7 8 9 10**
5. Overall, I invested substantial mental effort learning during this colonoscopy	**0 1 2 3 4 5 6 7 8 9 10**

St. Michael's

Inspired Care. Inspiring Science.

Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a consent form regarding the above mentioned research study. Before you give your consent to voluntarily participate in this study, it is important that you read the following information and ask the study personnel as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Background and Purpose of the Study

Colonoscopies are medical procedures that gastroenterology physicians and general surgeons learn during their residency training. Traditionally, these procedures are learned for the first time on patients in the clinical setting under the supervision of a fully-trained attending physician. Virtual reality (VR) has since been used to create devices, called endoscopic simulators that can emulate the look and feel of performing colonoscopies, and have been validated in research studies to confer basic skills to trainees. The optimal method to use virtual reality simulators for teaching trainees that have yet to begin procedures in colonoscopy has yet to be determined, and was identified by the American Society for Gastrointestinal Endoscopy as a need for further training.

The primary objective of this project is to evaluate the impact of a simulation-based training curriculum using gamification on clinical performance in colonoscopy.

Eligibility

You are asked to consider taking part in this study if you are a resident in General Surgery, Adult Gastroenterology or Pediatric Gastroenterology at the University of Toronto.

In order to be eligible for this study, you must be a post-graduate trainee in the above programs, must have completed less than 25 colonoscopic procedures, and must have completed less than 25 simulated colonoscopy procedures to date.

Description of the Study

We aim to recruit 36 postgraduate novice endoscopists from the Adult Gastroenterology, Pediatric Gastroenterology and General Surgery training programs at the University of Toronto. **Note:** this study takes place concurrently alongside the Annual Endoscopic Simulation Training Course. The study, as described below, is a randomized control trial that is investigating the effectiveness of a new simulation-based curriculum. The Annual Endoscopic Simulation Training Course is an educational program through the University of Toronto, which aims to teach novices how to perform colonoscopies. Participation in the study component is optional; if you chose to opt-out of the study, it will not impact your participation in the course.

You will be asked to take a written questionnaire at the start of the study to collect demographic and background information including: age, sex, level of training, previous endoscopy experience and nature of experience, and video game experience, which may correlate with baseline endoscopic skill.

Following this you will take part in a pre-test consisting of the following:

1. **Knowledge Test:** A 30 minute (17 questions) multiple-choice question test designed to assess participants' theoretical knowledge of colonoscopy, including indications, sedation, safety, findings, pathology and follow-up.

2. VR Simulation Test: This test will assess baseline endoscopic technical proficiency through the completion of a colonoscopy procedure on the VR simulator (EndoVR® Colonoscopy Module 3). This scenario simulates a screening colonoscopy, without the need for any type of intervention (such as biopsy). The time limit of the procedure will be 30 minutes. An expert rater will be present to assess performance, but will not provide assistance. You will be videotaped in order to obtain performance measures, such that your faces are not captured (to ensure anonymity). Prior to starting the procedure, you will complete a questionnaire to measure self-efficacy.

3. VR Simulation Based "Integrated Scenario" Test: Following the simulator-only test, participants will complete an Integrated Scenario format test to assess their baseline endoscopic non-technical proficiency. This simulated procedure will mimic the setup of an endoscopic suite, as the VR simulator will be positioned next to a patient bed. A standardized patient, who will receive instructions regarding their medical role, will act out a scenario on colon cancer screening. You will be expected to explain the colonoscopy procedure, its benefits and risks, and to obtain procedural consent. You will then carry out the procedure on the VR simulator (EndoVR® Polypectomy Module #3) while responding to the patient and interacting with the standardized nurse (SN) as appropriate. The Standardized Patient (SP) will act out cues from the VR simulator if the simulator signals that the procedure has exceeded its threshold for discomfort. Your performance will be videotaped (in a manner that their faces are not captured to ensure anonymity) in order to obtain performance measures. You will be given a maximum of 45 minutes to complete the procedure.

You will then be randomized, using an online randomization algorithm, to one of two groups:

1. Control Group: This group will receive 4 hours of interactive small-group didactic and hands-on sessions. During these sessions, participants will focus on learning about the theory of colonoscopy, including related concepts of pathology, anatomy, and therapeutic technique. The last session will focus on non-technical skills (NTS) relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. During this session, participants will also watch a video that demonstrates an ideal endoscopic procedure in terms of NTS, as well as learn about the "E-NTS Checklist", which will be provided for them to later use during the integrated scenario training. This checklist has been developed according to evidence-based recommendations and targets non-technical skills. After each didactic session, a short MCQ based on the topics covered in that session will be administered, in keeping with suggestions from the literature regarding "test-enhanced learning". In addition to didactic training, the control group will be given six hours of expert-assisted instruction on both the low-fidelity simulator (1 hour) and on the high-fidelity VR simulator (5 hours). Six modules of increasing difficulty in colonoscopy and colonoscopic polypectomy will be taught using one-on-one feedback from an expert academic endoscopist. The endoscopy instructor will demonstrate techniques, answer

questions and provide individualized performance feedback on global performance, with a focus on non-technical skills. During training on the high-fidelity simulator, the last two hours will take the form of the integrated scenario, which will feature a standardized patient (SP) and standardized nurse (SN). Terminal feedback will be given after each integrated scenario by the instructor. Finally, the "E-NTS Checklist" will be accessible during training in the integrated scenario, as participants can view the checklist prior to each case and review it after the case.

2. Intervention Group: This group will receive the same 4 hours of didactic teaching, and hands-on sessions. The intervention group will also receive the same teaching on both the low-fidelity and high-fidelity simulators. Within the context of the didactic sessions and simulator training, the GIC group will engaged in "gamified practice" in two ways. First, leaderboards will also be used to track and rank participants' performances. Prior to training, participants in the GIC group will watch a tutorial video on the functionality of the leaderboards and subsequently receive an anonymized ID tag that can be used to identify only their position on the leaderboard. Participants will also be informed that awards will be given to the individual who achieves first place. An "introductory" leaderboard, based on technical skills performance during the low-fidelity simulator practice, will be used to familiarize participants with the function of the leaderboard. After practice on the low-fidelity simulator is completed, participants will be introduced to the leaderboard for performance on the VR simulator and didactic sessions. Specifically, this leaderboard will include 4 components: a non-technical skills score, a technical skills score, a cognitive skills score,and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the M-OSANTS and JAG-DOPS, respectively, while the scoring of the cognitive skills will be based on percentage scores of the MCQ from the didactic sessions. Scores will be aggregated only from participants training on the same days. The leaderboard will be displayed on a central laptop and/or TV screen and will be accessible at any time throughout the day. Finally, participants in the GIC group will have the opportunity to be rewarded for their performances. One method of reinforcing good performance will be through achievement badges. These badges will be awarded after each scenario on the high-fidelity simulator and will be based on completion, proper technique, and/ or correct identification of pathology. Additionally, the participant who has accumulated the most badges will be awarded a prize.

A post-test will be administered after completion of the training period to compare learning between the two groups, consisting of:

1. Knowledge Test

Knowledge acquisition will be evaluated using a 30 minute (17 questions) multiple-choice question test designed to assess theoretical knowledge of colonoscopy.

2. Simulation-based Assessment

You will be assessed through the completion of a colonoscopy procedure on the VR simulator. As with the pre-test, the post-test will include an "integrated scenario" which links a standardized patient with the VR colonoscopy simulator. You will once again be required to explain the procedure, its benefits and risks, and obtain informed consent. You will then carry out the procedure on the simulator while responding to the patient as appropriate. Once again, the performance of all participants will be videotaped, such that their faces are not captured to ensure anonymity, in order to obtain performance measures.

3. Patient-based transfer test

You will then be contacted to undertake two colonoscopies on real patients. These procedures will be videotaped in a manner that anonymizes you and the patient. The videotapes will be assessed by two independent blinded expert endoscopists.

Potential Harms (Injury/Discomfort/Inconvenience)

There are no known harms associated with participation in this study.

Potential Benefits

You will not receive credit in performing colonoscopies by participating in this study. You may receive no direct benefits from being in this study. Results from this study will be used to adjust the structure and format of the current University of Toronto virtual-reality colonoscopy training curriculum for novice endoscopic trainees.

Confidentiality and Privacy

All the persons associated with this study, including the study investigators and delegates (study team) are committed to respecting your privacy. No information that discloses your identity will be published or released to any other persons without your consent unless required by law.

Video-recordings of your face are considered to be identifying personal information and will not be shown when videotaping these procedures. During the video-recordings, you are requested not to state your name or the names of anyone else or any institutions. However if this does happen, you should know that the audio track from the video will be removed so identifying information is removed.

Any records, documentation, or information related to you will be coded by study numbers to ensure that persons outside of the study will not be able to identify you. All study data forms will be identified by study code number and not by name. No identifying information about you will be allowed off site. All information that identifies you and study data will be securely stored at St. Michael's Hospital. The video recordings will be securely destroyed after data collection. Other identifying information will be securely destroyed after all the colonoscopy procedures have been completed. The study

data will be securely destroyed when the study results have been published, within five years after completion of the study.

It is important to understand that despite these protections being in place, experience in similar studies indicates that there is the risk of unintentional release of information. The principal investigator and study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will accidentally be given to someone else is minimal.

Data collected during this study will not form any part of your evaluation for the rotation and will not be forwarded to your program director or any other individual involved in your evaluation in residency. The study investigators will have access to the coded study data, but will not have access to your identifying information, including the video-recordings. The St. Michael's Hospital Research Ethics Board may have access to your identifying information and study data collected, for the purpose of study monitoring.

In no way does signing this consent form waive your legal rights nor release the investigators or involved institution from their legal and professional responsibilities.

Voluntary Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw or are withdrawn from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Study Results

We may present this study at a scientific conference and we intend to write an article about this study for a scientific journal. No identifying information about you will be revealed in any presentation or publication about the study. Study results will be communicated to you by request following completion of the study. You can ask for a copy of the published article by contacting Michael Scaffidi, Research Assistant, at (416) 864-5628 or by e-mail at scaffidim@smh.ca.

Potential Costs of Participant and Reimbursement to the Participant

Participating in this study will not result in any costs charged to you, and as such, no reimbursements or compensation will be provided.

Sponsor

This study is funded by a grant from the University of Toronto.

Compensation for Injury

If you suffer a physical injury from (the procedure(s) or participation) in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your participation in the Annual Endoscopic Simulation Course, clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Can Participation in this Study End Early?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact the Research Coordinator, Michael Scaffidi, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions

Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, you may contact the Chair of the Research Ethics Board, St. Michael's Hospital at 416-864-6060 ext. 2557 during regular business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

Study Contacts

If you require further information, or have any questions concerning this study, please contact the principal investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Collect calls will be accepted.

You may also contact the research assistant, Michael Scaffidi, at (416)-864-5628 or by e-mail at scaffidim@smh.ca.

You will be given a copy of this consent form to keep for your own records.

Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

Principal Investigator
Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
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Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Declaration of Consent

The research study has been explained to me, and any questions that I have asked about the study have been answered to my satisfaction. A member of the study team, who has no influence on my academic program, will be obtaining my consent form. I have the right not to participate and the right to withdraw from this study without affecting my participation in the Annual Endoscopic Simulation Course, evaluation or standing on my academic program at the University of Toronto, or any admission to (or current status in) a residency/fellowship program. I have also been informed that my choice will not affect my current or future employment at St. Michael's Hospital. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators or involved institution from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me in this study will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission unless required by law. I have been given sufficient time to read the above information. I consent to participate in this study. I will be given a signed copy of this consent form.

Name of Participant (print)	Signature	Date

I have explained the study to the above-named participant and discussed the potential risks and benefits (if any) associated with participation in this research study. I have answered all questions asked with respect to this research study.

Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Consent Discussion	Date

St. Michael's
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Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
Patient participants

This is a consent form regarding the above mentioned research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Before you give your consent to be a volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

CONFLICTS OF INTEREST
We have no known actual, apparent, potential or perceived conflicts of interest in conducting this study.

FUNDING SOURCE

This study is funded by a grant provided by the University of Toronto, Division of Gastroenterology.

PURPOSE OF THE RESEARCH
You are being asked to consider participating in this study because you are booked to have a colonoscopy.

Colonoscopy is a technically challenging procedure and it requires considerable training to learn the skill. Increasingly trainees that learn these skills are learning them on high-fidelity virtual reality simulators that have been designed to teach colonoscopy, prior to performance on real patients. Although simulation-based practice is being integrated into endoscopy training curricula, there is no consensus on the best way to how to do this. One method that has been used in surgical simulation is to interlace a lecture-based curriculum with supervised procedures with feedback with experts. It is unknown whether this provides better learning than self-directed endoscopic procedural learning.

The purpose of this study is to compare performance on colonoscopies performed on a virtual reality endoscopic simulator between two groups of beginning endoscopists, one trained with a curriculum that using gamficiation and one trained with a curriculum that uses conventional simulationtraining.

DESCRIPTION OF THE RESEARCH

WHAT WILL HAPPEN DURING THIS STUDY?

Two physician assessors will be asked to evaluate the performance of the physician performing your colonoscopy. In order to assess the performance, videotaping is required. The physicians will use standardized tests for performance of colonoscopy in order to perform the assessment. To ensure anonymity, your face and the endoscopist's face will not be recorded. Two views of the procedure will be captured at the same time: 1) a close-up view of the endoscopist's gloved hands using the control knobs and tube of the colonoscope and 2) the view obtained by the colonoscope's camera which shows the inside of the your bowel.

You will be asked, in person, to provide some personal health information including your age, gender, the reason why you having the colonoscopy procedure and if you have any history of a difficult colonoscopy or if you have had surgery in the past to remove part of your bowel.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

It is anticipated that about 120 people (80 patients and 40 endoscopists) will participate in this study at St. Michael's Hospital. The study is expected to take three years to complete.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

All data will be collected during your scheduled colonoscopy procedure time. Participation in this study will take no additional time and the duration of your colonoscopy procedure itself will not be affected.

If you decide to participate in this study you will be asked to do the following:

(1) Provide one of the study investigators, in person, with some personal health information including your age, gender, the reason why you are having the colonoscopy procedure and if you have any history of a difficult colonoscopy or have had surgery in the past to remove part of their bowel.

(2) Agree to allow your colonoscopy procedure to be videotaped during this study. Your name and face will not be shown to the camera.

POTENTIAL HARMS (Injury, discomfort, inconvenience)

You may experience side effects from participating in this study. Some of these risks we know about. There is also the possibility of risk that we do not know about or have not seen in study subjects to date. Some of these can be managed. If you decide to take part in this study, you should contact Dr. Samir C. Grover (Division of Gastroenterology, St. Michael's Hospital, 416-864-5628) if you think you have side effects even if you think it has nothing to do with the study.

The risks we know of are:

There are no direct short- or long-term risks anticipated. Data collected will be kept completely confidential and anonymous. Even though the risk that a participant's data could become public is very small, it can never be completely eliminated. However, every precaution is taken to prevent this. Any data collected during the study (e.g. performance assessments, videotaped performance) will be identified using only an individualized number known only to the principal investigator (Drs. Grover) so that your privacy is protected.

POTENTIAL BENEFITS

There is no benefit to you from your participation in this study.

PROTECTING YOUR INFORMATION

You have the right to have any information about you that is collected, used or disclosed for this research study to be handled in a confidential manner. No information that discloses your identity may be released or published without your consent. All information obtained during the study will be held in strict confidence. Even though the risk that your data could become public is very small, it can never be completely eliminated. However, every precaution is taken to prevent this. Prior to starting the study, you will be assigned a unique code known only to the principal investigator (Dr. Grover) so that your privacy is protected. Any data collected during the study will be identified using only this code.

The file which links your unique study identifier with your name is the only source of information that could possibly be utilized, either alone or with other information, to identify you. This encrypted file will be kept behind locked doors in Dr. Samir Grover's office, St. Michael's Hospital until data analysis is complete (anticipated time frame: 5 years). After that time it will be securely destroyed as per hospital requirements. Only Dr. Grover (principal investigator) will have access to this file.

Any study data about you that is sent outside of the hospital will be aggregate data for research presentations and publications. No individual level data will be reported .

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, including personal health information, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. Experience in similar studies indicates that the

greatest risk in this study to you is the unintentional release of information from your health records. The study doctor will protect your records and keep confidential all the information in your study file, including your name, address and telephone number. The chance that this information will accidentally be given to someone else is small.

You have the right to have any information about you and your health that is collected, used or disclosed for this research study to be handled in a confidential manner.

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your name, address, date of birth, new or existing medical records, that includes types, dates and results of medical tests or procedures.

Access to your personal health information will take place under the supervision of the Principal Investigator. The information that is collected for the study will be kept in a locked and secure area by the study doctor for 5 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the St. Michael's Hospital Ethics Board, a group of people who oversee the ethical conduct of research studies at St. Michael's Hospital

The investigators plan to publish the results of this study. You will not be named in any reports, publications, or presentations that my come from this study. Only group data will be presented.

STUDY RESULTS

As mentioned, the investigators plan to publish the results of this study. Once the study has been completed, you can contact Dr. Samir C. Grover (416-864-5628) to obtain a copy of the results.

POTENTIAL COSTS OF PARTICIPATION AND REIMBURSEMENT TO THE PARTICIPANT

You will not have to pay for any of the procedures involved in this study. There is no reimbursement associated with participation in this study.

COMPENSATION FOR INJURY

If you suffer a physical injury from participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study investigators, sponsors, or other involved institutions from their legal and professional responsibilities.

PARTICIPATION AND WITHDRAWAL

Participation in any research study is voluntary. If you choose to participate in this study, you can change your mind without reason and withdraw from the study any time up to 5 years. After 5 years, your data will be anonymized and it will no longer be possible to identify which data are yours. In addition, it you decide to decline participation or withdraw from the study at any time, this will have no impact on the care you or your family will receive at St. Michael's Hospital.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact Dr. Samir C. Grover, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions.

RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding your rights as a research participant, you may contact Chair of the Research Ethics Board at 416-864-6060 ext. 2557 during business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

STUDY CONTACTS

If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Samir C. Grover at 416-864-5628.

INFORMED CONSENT

Study Title: Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

Principal investigator: Dr. Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology, Department of Medicine
St. Michael's Hospital, University of Toronto
416-864-5628 (available Mon to Fri 9:00 AM – 5:00 PM)

The research study has been explained to me and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions of their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that study records relating to me will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told that I will be given a signed copy of this consent form.

_____ _____
Signature Date

☐ I **agree** to allow my colonoscopy procedure to be videotaped during this study as described in this consent form.

☐ I **do not agree** to allow my colonoscopy procedure to be videotaped during this study as described in this consent form.

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____ _____ _____
Name of person obtaining consent (print) Signature Date

ASSISTANCE DECLARATION □ (check here if not applicable)

The participant/substitute decision-maker was assisted during the consent process as follows (please check the relevant box and complete the signature space below):

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered..

I have been requested to interpret the consent discussion for the potential research participant (_____). I am competent in the English language and in the language of choice of the potential participant (_____). I am not involved in the research study. I agree to keep confidential all personal information of the potential participant. I have interpreted the consent discussion. The potential participant has advised me in his/her own language that he/she has been informed about the research study, the nature and extent of his/her participation, including the risks involved. The potential participant freely gives his/her consent to participate in this study.

_____	_____	_____	
Printed Name of Interpreter	Signature	of Interpreter	Date

_____	_____
Relationship or Position of Interpreter	Contact Information of Interpreter

☐ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant/substitute decision-maker.

_____	_____	_____ Print
Name of Witness	Signature	Date

_____
Relationship to Participant

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

Protocol for a randomized trial evaluating the effect of applying gamification to simulation-based endoscopy training

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Protocol for a randomized trial evaluating the effect of applying gamification to simulation-based endoscopy training

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Data acquisition: Scaffidi, Khan, Walsh, Winger, Kalaichandran, Lin, Grover
Analysis and interpretation of data: Scaffidi, Khan, Walsh, Grover
Drafting of the manuscript: Scaffidi, Khan, Walsh, Grover,
Critical revision of the manuscript for important intellectual content: Scaffidi, Khan, Walsh, Pearl, Winger, Kalaichandran, Lin, Grover
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Abstract

Background: Simulation-based training provides a safe environment and effective means to enhance skills development. Simulation-based curricula have been developed for a number of procedures, including gastrointestinal endoscopy. Gamification, which is the application of game-design principles to non-game contexts, is an instructional strategy with potential to enhance learning. No studies that have investigated the effects of a comprehensive gamification curriculum on the acquisition of endoscopic skills among novice endoscopists.

Methods and analysis: Thirty-six novice endoscopists will be randomized to one of two endoscopy simulation-based training curricula: (1) the Conventional Curriculum Group, in which participants will receive 6 hours of one-on-one simulation training augmented with expert feedback and interlaced with 4 hours of small group teaching on the theory of colonoscopy; or (2) the Gamified Curriculum Group, in which participants will receive the same curriculum with integration of the following game-design elements: a leaderboard summarizing participant performance, game narrative, achievement badges, and rewards for top performance. In line with a progressive learning approach, simulation training for participants will progress from low to high complexity simulators, starting with a bench top model and then moving to the EndoVR® virtual reality simulator. Performance will be assessed at three points: pre-training, immediately post-training and 4-6 weeks after training. Assessments will take place on the simulator at all three time points and transfer of skills will be assessed during two clinical colonoscopies 4-6 weeks post-training. Mixed factorial ANOVAs will be used to determine if there is a performance difference between the two groups during simulated and clinical assessments.

Ethics and dissemination: Ethical approval was obtained at St. Michael's Hospital. Results of this trial will be submitted for presentation at academic meetings and for publication in a peer-reviewed journal.

Strengths and limitations of this study

- The intervention in this randomized trial is a comprehensive gamified simulation-based curriculum in gastrointestinal endoscopy that includes a game narrative, performance tracking measures, and rewards. These game-design elements are grounded in educational theory.
- The primary outcome is clinical performance of live colonoscopies on real patients, which will be assessed by two blinded independent expert endoscopists using an assessment tool with strong validity evidence.
- Participants will be assessed immediately after training for skill acquisition, and 4-6 weeks after training to evaluate skill retention and transfer of skills to the clinical environment.
- There are significant human resources required for implementation with respect to tracking participants' game metrics and adjusting leaderboards.

Key Words: simulation; colonoscopy; gamification; skill acquisition

Introduction

Simulation-based training (SBT) provides a safe and effective means to enhance skills development in gastrointestinal endoscopy.[1,2] SBT is more effective when embedded within a curriculum that is grounded in educational theory.[3–6] While previous studies have demonstrated the effectiveness of comprehensive structured curricula and curricula based on a progressive learning approach[4,7], other instructional strategies may further enhance procedural skills training.

One such enhancement may lie in gamification. Gamification refers to the application of game design elements, (conceptual building blocks central to creating successful games) to traditionally non-game contexts.[8–10] The overall purpose of gamification is to "encourage behavioral change and promote desired attitudes."[11] Gamification has previously been applied in health-related settings such as health promotion and e-health.[12–14] More recently, it has been gaining traction in the medical education setting, as gamification has the potential to improve learning and learner attention, engagement, motivation and behaviour change.[8,15] In a recent randomized trial, participants were ranked on a leaderboard as they completed cardiopulmonary resuscitation (CPR) training.[16] After training, participants who were ranked on a leaderboard had significantly better technical skills acquisition on the CPR training device. Another recent trial evaluated the effect of competition on novices' ability to learn simulated laparoscopic cholecystectomy.[17] The authors found that participants who engaged in competition demonstrated fewer movements and a shorter path length, suggesting increased efficiency.

While these reports highlight the potential benefits of gamification in educational contexts, the use of leaderboards and competition represent narrow applications of gamification. To date, there are no studies that have investigated the application of a comprehensive gamified curriculum that integrates multiple game design elements for procedural learning in medicine. Additionally, no studies have reported clinical outcomes on real patients. To bridge these gaps, we aim to determine the impact of a gamified simulation-based curriculum in endoscopy on clinical performance, compared to an identical curriculum that does not incorporate game design elements.

Methods & Analysis

Study Design

This single-blinded, parallel group, randomized controlled trial (RCT) is currently being conducted at St. Michael's Hospital in Toronto, Canada. Recruitment started June 2017. The methodology was adapted from previous studies by our group.[3,4,18] We used the SPIRIT checklist when writing our report.[19] The study design is summarized below in **Figure 1**.

Participants

Thirty-six novice endoscopists (performed < 25 previous real and/or simulated colonoscopies) will be recruited by one author (MAS). Participants will be included if they are from the general surgery or gastroenterology residency programs at the University of Toronto. Participants will be excluded if they have performed greater than 25 previous real and/or simulated colonoscopies.

Simulators

Bench Top Simulator

The bench top colonoscopy simulator is comprised of a series of vertical wooden barriers with numbered holes conforming to 27 different sequences of varying complexity. Participants use a real videocolonoscope, which provides visual output, to navigate through each sequence. This bench top endoscopy simulator helps develop general endoscopic skills and has shown good validity evidence for training novices.[20]

Virtual Reality Simulator

The EndoVR® virtual reality (VR) endoscopy simulator (CAE Healthcare, Montreal) is used for the VR training and all simulator tests. It models navigation through a colon, using a specialized endoscope that is inserted into a computer-based module with a screen showing

the colonic lumen of a virtual patient. It provides visual and haptic feedback related to the procedure. The simulator has several standardized case-based scenarios of varying complexity for colonoscopy and has robust validity evidence in the context of novices.[21,22]

Experimental Design

(1) Baseline questionnaires

Participants will complete a questionnaire to collect baseline demographic information, including age, sex, level of training, and previous endoscopic experience. Questions regarding experience with team sports and video games will also be included, as these may correlate with baseline endoscopic skil[23] (**Appendix 1**). Additionally, scales assessing the following variables will be administered: (1) competitiveness (Revised Competitiveness Index, **Appendix 2**); (2) self-efficacy (adapted General Self-Efficacy Scale, **Appendix 3**); and (3) game-type personality (Gamified User Personality Hexad, **Appendix 4**). All the included scales have good validity evidence.[24–26]

(2) Pre-test

Participants will complete a series of assessments prior to training to assess (1) their baseline knowledge of colonoscopy (knowledge test); (2) technical skills (VR simulation test); and (3) non-technical skills (VR simulation "integrated scenario" test). No feedback will be provided at any point during these assessments.

1. *Knowledge Test:* A 30-minute, 17 item multiple choice question (MCQ) test designed to assess core concepts related to colonoscopy, including indications, pathology, and theory underpinning non-technical skills (**Appendix 5**).
2. *VR Simulation Test:* A colonoscopy procedure on the VR simulator with a time limit of 30 minutes. Baseline technical proficiency will be assessed by an expert endoscopist. The procedure will be video-recorded, with identifying features hidden, to allow for a blinded assessment at a later time.[27]
3. *VR Simulation "Integrated Scenario" Test:* A test in which participants will complete a colonoscopy procedure on the VR simulator in a naturalistic setting (i.e., endoscopy suite) while interacting with a standardized nurse and standardized patient.[28] Trainees will be expected to take a brief patient history and obtain informed consent. The trainee will then carry out the procedure (EndoVR® Module 3 - Polypectomy) as described above while responding to the patient and interacting with the nurse as appropriate. As in the technical test, performance will be assessed in real time and videotaped, ensuring anonymity is preserved.

(3) Training intervention

Following the pre-tests, participants will be randomized to one of two training groups, following a 1:1 allocation distribution
with no stratification. One author (RK) used an online sequence generator (https://www.random.org/sequences/) to generate a random sequence of numbers and placed labels with these numbers into sealed envelopes. Another author (MP), not involved in sequence generation, distributed the sealed envelopes to participants as they arrived for the course. The first author (RK) was not present during envelope distribution. Investigators were blinded to group allocation.

1. *Conventional Curriculum (controls)***:** The control group will receive a total of four, one-hour, small-group teaching sessions covering the theory of colonoscopy, including pathology, anatomy, and therapeutic technique. One session is dedicated to non-technical skills relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. In this session, participants will watch a video demonstrating ideal endoscopic non-technical skills and learn about the Endoscopic Non-Technical Skills (E-NTS) checklist which will be provided for them to use during the integrated scenario training (**Appendix 6**). This checklist was developed in accordance with evidence-based recommendations, and outlines key endoscopic non-technical skills.[29] Following each teaching session, a short MCQ test on the topics covered in that session will be administered, in keeping with the "test-enhanced learning" literature.[30] In addition to teaching sessions, the control group will be given a total of six hours of expert-assisted instruction on both the bench top simulator (1 hour) and the VR simulator (5 hours).

Six modules of increasing difficulty in colonoscopy will be taught with one-on-one feedback from an expert academic endoscopist. The instructor will demonstrate techniques, answer questions and provide individualized performance feedback with a focus on non-technical skills. The last two hours of training on the VR simulator will consist of integrated scenarios, which feature a standardized patient and nurse. Following each scenario, the instructor will debrief the trainee on their performance, using the "E-NTS Checklist" as a framework for discussing their non-technical skills.

2. *Gamified Curriculum (GC):* This group will receive the same 4 hours of small group teaching and 6-hours of hands-on simulator training. Within the context of the teaching sessions and simulator training, the gamified curriculum will incorporate the following game design elements: a game narrative; performance tracking measures; and rewards. First, a game narrative will underlie the delivery of the gamified curriculum. Participants will be assigned an avatar and will be tasked with completing a journey of the avatar around a game-board shaped like the colon (**Appendix 7**) with the goal of reaching the final destination, the terminal ileum. Second, performance tracking measures will be used to allow participants to gauge their performance over time. These measures will be summarized on a leaderboard, which will include 4 components: a non-technical skills score; a technical skills score; a cognitive skills score; and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the Modified Objective Structured Assessment of Non-Technical Skills (MOSANTS) (**Appendix 8**) and the Joint Advisory Group for Gastrointestinal Endoscopy's Direct Observation of Procedural Skills (JAG DOPS) tool (**Appendix 9**), respectively. Scoring of cognitive skills will be based on MCQ test scores from the teaching sessions. Scores will be aggregated on the leaderboard for participants training on the same days. The leaderboard will be presented to participants after they finish each hour of practice. Finally, participants will engage in a system of both short-term and long-term rewards. One short-term reward will involve badges to recognize achievements of procedural benchmarks (e.g. cecal intubation) (**Appendix 10**). Another short-term reward will be the assignment of a wearable medallion, which will be given to the participant with the highest overall ranking at the end of each hour of practice. The long-term reward will be a low-cost prize (i.e. less than $25 CAD) given to the participant with the highest overall ranking throughout practice. All three game design elements (game narrative, performance tracking measures, reward system) will be introduced to participants in the gamified curriculum group prior to training with a brief tutorial video. After watching the video, participants will receive an anonymized ID to allow for self-tracking on the leaderboard while keeping individual scores private.

   All three game design elements are consistent with recommendations from the gamification and educational literature. In line with self-determination theory, leaderboards are purported to increase users' sense of relatedness, engagement and competence through social comparison, feedback provision and documentation of achievement.[31] The rationale for achievement badges and other rewards is that they serve as visual symbol of attained goals, thus supporting participants' sense of competence and serving to foster external motivation and engagement[31,32]. Finally, game narratives are thought to enhance engagement through the integration of meaning and interaction.[9] These elements must be carefully calibrated to challenge and engage learners appropriately and to ensure maintenance of learners' intrinsic motivation.[8,15]

(4) Post-test

Participants will complete a series of assessments immediately after training (immediate post-test). These will assess: (1) knowledge acquisition; (2) technical skills acquisition; and (3) non-technical skills acquisition. They will include the same *Knowledge Test*, *VR Simulation Test*, and *VR Simulation "Integrated Scenario" Test* that participants will complete during the *Pre-test.*

(5) Delayed testing (Retention and Transfer)

Participants will complete a series of assessments 4 to 6 weeks after training to assess their retention and transfer of skills. These will assess the following: (1) knowledge retention; (2) technical skills retention; (3) non-technical skills retention; and (4) transfer of skills to the

clinical environment. They will include the same *Knowledge Test*, *VR Simulation Test*, and *VR Simulation "Integrated Scenario" Test* that participants will complete during the *Pre-test* and the *Post-test*. To assess for transfer of skills to the clinical environment, participants will also complete two live colonoscopies on real patients. . These two procedures occurred simultaneously on a single day between 4 and 6 weeks after completion of training .These procedures will be videotaped in a manner that anonymizes the identity of the participant and the patient. Procedures on patients with a history of colonic or pelvic surgery or difficult colonoscopy will be excluded. Sedation and monitoring will be carried out according to standard practices on the endoscopy unit. An experienced attending endoscopist (completed > 500 previous colonoscopies) will provide verbal and/or hands-on assistance as necessary and take over if the participant cannot complete the procedure, or if any concerns regarding patient safety ariose. All patients were consented for the use of their procedure in this study.

Patient and Public Involvement

We based our approach to patient involvement on previously published studies focusing on clinical outcomes for endoscopic training[3,4], Specifically, patient involvement will be limited to their participation in the primary outcome, which involves assessment of clinical colonoscopies by study participants. Patients will not be required to evaluate the impact of the intervention. There will be no public involvement.

Primary outcome measure

The primary outcome measure is clinical performance during two live colonoscopies 4 to 6 weeks after training, as assessed by the JAG DOPS.[33]. Each clinical colonoscopy will be independently assessed by two experienced endoscopists who will be blinded to group assignment. One rater will be present during the procedure and the other rater will assess the participant's performance using the video-recorded procedure. Video-based assessment of endoscopic performances has been shown to have good validity evidence, compared to live assessment.[27]

Secondary outcome measures

1. Knowledge acquisition, as assessed by the MCQ Knowledge Tests
2. Technical skills acquisition during the VR Simulation Tests, as assessed by the JAG DOPS (**Appendix 9)**
3. Non-technical skills acquisition during the Integrated Scenario Test, as assessed by the Modified Objective Structured Assessment of Non-Technical Skills (M-OSANTS) for colonoscopy, which has good validity evidence for surgery and was modified for endoscopy[5] (**Appendix 8)**
4. Patient comfort during the clinical colonoscopies, as assessed by the endoscopy nurses using the Nurse-Assessed Patient Comfort Score (NAPCOMS)[34] **(Appendix 11**)

Exploratory outcome measures

5. Participant self-efficacy after each simulated and clinical colonoscopy testing procedure, as measured by an adapted General Self-Efficacy Scale[25] (**Appendix 3**)
6. Cognitive load after each simulated and clinical colonoscopy testing procedure, as measured by the Cognitive Load Scale for Colonoscopy[35] (**Appendix 12**)
7. Participant competitiveness after each simulated and clinical colonoscopy testing procedure, measured using the Revised Competitiveness Index[24] (**Appendix 2**).

Experienced endoscopists will assess participants' technical skills and non-technical skills during the pre-training, immediate and delayed post-training simulation-based assessments.

Data Management

Data will be collected through paper forms directly from assessors. Data from the forms will be extracted and input into a database on a password-protected computer. There is no requirement for a data monitoring committee as this is not a trial addressing the efficacy of a treatment nor is patient safety at risk. Details with respect to protection of confidentiality of participant data is outlined in the participant and patient consent forms (**Appendix 13,**

Appendix 14).

Analysis Plan
Statistical analyses will be performed using SPSS version 20 (SPSS, Inc, Chicago, IL). Alpha for all statistical tests will be set at 0.05. For all primary and sub-group analysis, appropriate measures will be taken to minimize an inflated Type I error due to multiple comparisons.

Baseline Questionnaire: Participant baseline variables will be characterized with descriptive statistics, using mean with standard deviation for continuous variables and number frequency for categorical variables, respectively.

Clinical Performance: Performance during the live colonoscopies will be compared between the two groups using the JAG DOPS, NAPCOMS, and MOSANTS scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (procedure 1 vs. procedure 2) analysis of variance (ANOVA) will be used. ANOVA differences significant at $P < 0.05$ will be further analyzed using Tukey honestly significant difference (HSD) post hoc tests. In addition, sensitivity analyses of the mixed factor ANOVA will be performed with gender and residency program (i.e. gastroenterology, general surgery) as covariates, as previous literature has identified gender differences in the acquisition of surgical skills[36].

Technical Performance*:* Differences in technical skills acquisition on the simulator will be determined by comparing JAG DOPS scores between groups. Specifically, a mixed factor 2 (Gamified vs. Conventional Curriculum) x 3 (pre-test, post-test, retention test) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Non-Technical Skill Performance: Differences in non-technical skills acquisition on the simulator will be determined by comparing MOSANTS scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 3 (pre-test, post-test, retention test) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Competitiveness: Baseline competitiveness, as measured by the Revised Competitiveness Index and the Gamification User Types Hexad, will be compared between groups using an independent t-test for each index.

Self-efficacy: Differences in self-efficacy between groups will be determined by comparing General Self-Efficacy Scale scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (pre-course vs. post- course) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Cognitive Load: Differences in cognitive load between groups will be determined by comparing Cognitive Load Index of Colonoscopy scores. A mixed factor 2 (Gamified vs. Conventional Curriculum) x 2 (pre-course vs. post- course) ANOVA with Tukey's HSD post-hoc tests will be conducted.

Sample size estimation
Since there are no prior studies investigating a gamified curriculum for procedural learning, we conducted the power analysis based on the effect size from a previous study that evaluated an SBT curriculum for endoscopy.[3] Based on an effect size of 1.0 (Cohen's d), an alpha of 0.05 (two-tailed), a beta of 0.10, 2 groups, and 2 measurements, a minimum of 17 participants will be required to achieve a power of greater than 0.90 using repeated measures ANOVA (between-factors). To accommodate for a potential 5% dropout and/or non-response, we will recruit a total of 36 participants.

Ethics and Dissemination
Research ethics approval was granted by the St. Michael's Hospital Research Ethics Board (17-092). Protocol version 1.0, dated March 23, 2017, was approved. If any protocol modifications are needed, they will be made after communication with the research ethics board and will be detailed in any subsequent publications. Informed consent will be obtained from endoscopist participants and patients on whom participants will perform colonoscopies by one author (MAS). No personal health data on patients will be collected. All authors will have access to trial data. We will disseminate the results of the study through peer-reviewed

publication in journals and at scientific meetings. We do not plan to make participant-level data publicly available. The trial is registered at clinicaltrials.gov NCT03176251

Feasibility

To date, 21 participants have been recruited, randomized and have completed the study. Data collection is ongoing and is intended to reach completion by August 2018. Subsequent data analysis, manuscript writing and submission for publication are anticipated to reach completion by July 2019.

Discussion

The use of SBT for procedural skills training is widespread. In the report commissioned by the Future of Medical Education in Canada Postgraduate Project, the authors conclude that "simulation… needs to be integrated more thoughtfully into postgraduate curricula."[37] We aim to respond to this call through the development of an SBT curriculum grounded in educational theory. The strengths of this study lie in its randomized design and incorporation of various game design elements into the curriculum. Additionally, the primary outcome is measured in the clinical setting by two blinded expert assessors using an assessment tool with strong validity evidence. Finally, participants will be assessed both immediately after training for skill acquisition, and 4-6 weeks after training to evaluate skill retention and skill transfer to the clinical environment. There are several limitations of this study. First, this methodology requires substantial human resources to track participants' game metrics and adjust the leaderboards accordingly. Second, participants who are wearing the medallion that signifies high-ranking performance are potentially identifiable as being in the intervention arm. We do not, however, anticipate that this will impact outcome measures because the medallion is not visible on the video-recordings of the procedures. Furthermore, it is not worn during live colonoscopies. Finally, participant frustration, which may impact performance, is not included as an outcome measure.

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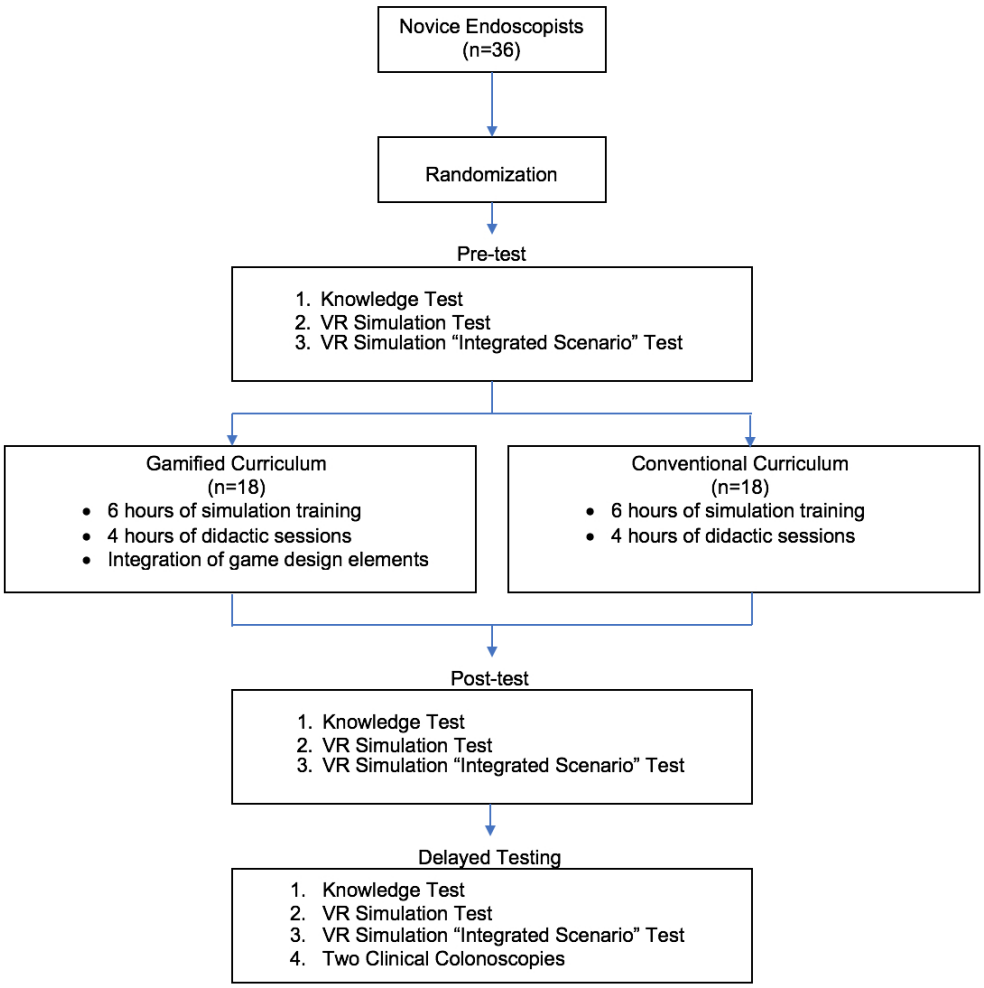
FIGURES

Figure 1: Study design.



Study design

195x198mm (144 x 144 DPI)

APPENDIX I:

BASELINE QUESTIONNAIRE

Participant ID Number: _____

1) Sex: □ Female □ Male

2) Age: _____

3) Handedness: □ Right □ Left □ Ambidextrous

4) Year of graduation from Medical School: _____

5) Programme:

□ Adult Gastroenterology
□ Pediatric Gastroenterology
□ General Surgery
□ Other (please specify: _____)

6) Level of training:

□ PGY 1
□ PGY 2
□ PGY 3
□ PGY 4
□ PGY 5
□ Other (please specify: _____)

7) Do you have previous experience in playing video games? □ Yes □ No

If yes, please specify:

(a) How many hours do you play on average per week? _____

(b) What types of games do you play? □ Sports □ Role-playing □ Real-time strategy □ Other (please describe)

8) Do you have previous experience in performing gastrointestinal endoscopy in the clinical or simulated setting? □ Yes □ No

If yes, please specify:

(c) Number of previous upper endoscopies in the ***clinical*** setting (attempted or completed): _____

(d) Number of previous upper endoscopies in the ***simulated*** setting (attempted or completed): _____

(e) Number of previous colonoscopies in the ***clinical*** setting (attempted or completed): _____

(f) Number of previous colonoscopies in the ***simulated*** setting (attempted or completed): _____

(g) Number of previous sigmoidoscopies in the ***clinical*** setting (attempted or completed): _____

(h) Number of previous sigmoidoscopies in the ***simulated*** setting (attempted or completed): _____

(i) Number of other ***clinical*** GI endoscopy procedures (please specify procedure): _____

_____
_____

(j) Number of other ***simulated*** GI endoscopy procedures (please specify procedure): _____
_____
_____

Competitiveness Scale

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
I like competition	1	2	3	4	5
I am a competitive individual	1	2	3	4	5
I enjoy competing against an opponent	1	2	3	4	5
I don't like competing against others	1	2	3	4	5
I get satisfaction from competing with others	1	2	3	4	5
I find competitive situations unpleasant	1	2	3	4	5
I dread competing against others	1	2	3	4	5
I try to avoid competing with others	1	2	3	4	5
I often try to outperform others	1	2	3	4	5
I try to avoid arguments	1	2	3	4	5
I will do almost anything to avoid an argument	1	2	3	4	5
I often remain quiet rather than risk hurting another person	1	2	3	4	5
I don't enjoy challenging others even when I think they are wrong	1	2	3	4	5
In general, I will go along with the group rather than create conflict	1	2	3	4	5

The General Self-Efficacy Scale

Please rate the following items based on a 4-rank scale.

1= Not at all true 2= Hardly true 3= Moderately true 4= Exactly true

	RATING
I can always manage to solve difficult problems if I try hard enough.	
If someone opposes me, I can find the means and ways to get what I want.	
It is easy for me to stick to my aims and accomplish my goals.	
I am confident that I could deal efficiently with unexpected events.	
Thanks to my resourcefulness, I know how to handle unforeseen situations.	
I can solve most problems if I invest the necessary effort.	
I can remain calm when facing difficulties because I can rely on my coping abilities.	
When I am confronted with a problem, I can usually find several solutions.	
If I am in trouble, I can usually think of a solution.	
I can usually handle whatever comes my way.	

Gamification User Types Hexad Personal Questionnaire

	Strongly Agree	Agree	More or less agree	Undecided	More or less disagree	Disagree	Strongly disagree
It makes me happy if I am able to help others	1	2	3	4	5	6	7
I like helping others to orient themselves in new situations	1	2	3	4	5	6	7
I like sharing my knowledge	1	2	3	4	5	6	7
The wellbeing of others is important to me	1	2	3	4	5	6	7
Interacting with others is important to me	1	2	3	4	5	6	7
I like being part of a team	1	2	3	4	5	6	7
It is important to me to feel like I am part of a community	1	2	3	4	5	6	7
I enjoy group activities	1	2	3	4	5	6	7
It is important to me to follow my own path	1	2	3	4	5	6	7
I often let my curiosity guide me	1	2	3	4	5	6	7
I like to try new things	1	2	3	4	5	6	7
Being independent is important to me	1	2	3	4	5	6	7
I like defeating obstacles	1	2	3	4	5	6	7
It is important to me to always	1	2	3	4	5	6	7

carry out my tasks completely							
It is difficult for me to let go of a problem before I have found a solution	1	2	3	4	5	6	7
I like mastering difficult tasks	1	2	3	4	5	6	7

I like to provoke	1	2	3	4	5	6	7
I like to question the status quo	1	2	3	4	5	6	7
I see myself as a rebel	1	2	3	4	5	6	7
I dislike following rules	1	2	3	4	5	6	7

I like competitions where a prize can be won	1	2	3	4	5	6	7
Rewards are a great way to motivate me	1	2	3	4	5	6	7
If the reward is sufficient I will put in effort	1	2	3	4	5	6	7
Return of investment is important to me	1	2	3	4	5	6	7

Endoscopy Knowledge Post-Test

This is the knowledge test for the University of Toronto endoscopic simulation course. Please type in your "endo" number to begin the test. The test consists of 17 questions for a total of 20 points.

The knowledge questions are on the next two pages. You have 30 minutes to answer these questions.

These answers are confidential, and your responses and score are only for the purposes of our research studies. They will not be used as part of your residency training assessments, or as part of competency assessments.

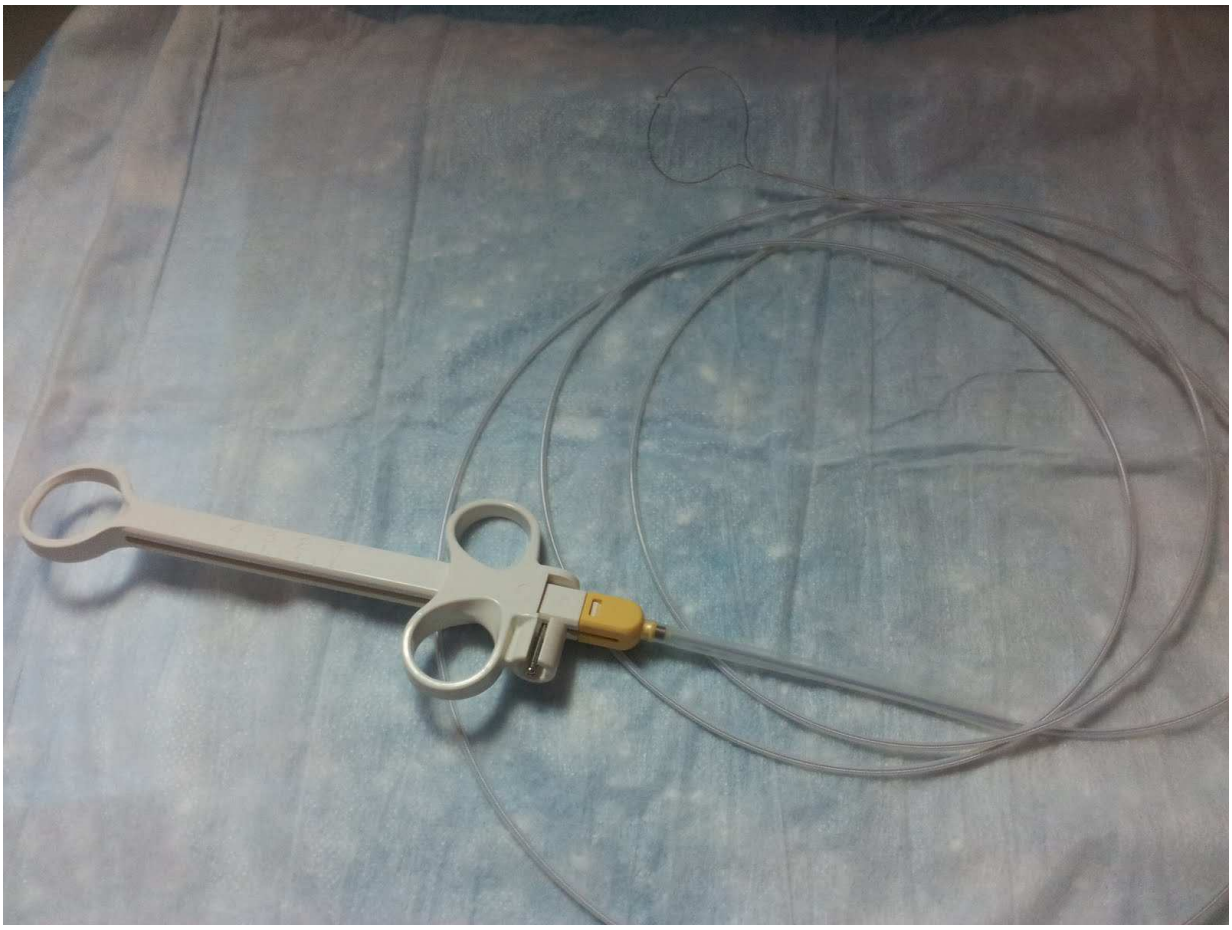
*Required

1. **Please type in your "endo" number login to start** *
   ie, "Endo10"

Endoscopic Knowledge Test (page 1 of 2)

2. **Question 1 (1 point)**
   Name the endoscopic device depicted below.
   Mark only one oval.

   - A. Endoloop
   - B. Endoscopic snare
   - C. Endoscopic biopsy forceps
   - D. Gold probe
   - E. Oval probe



3. **Question 2 (1 point)**

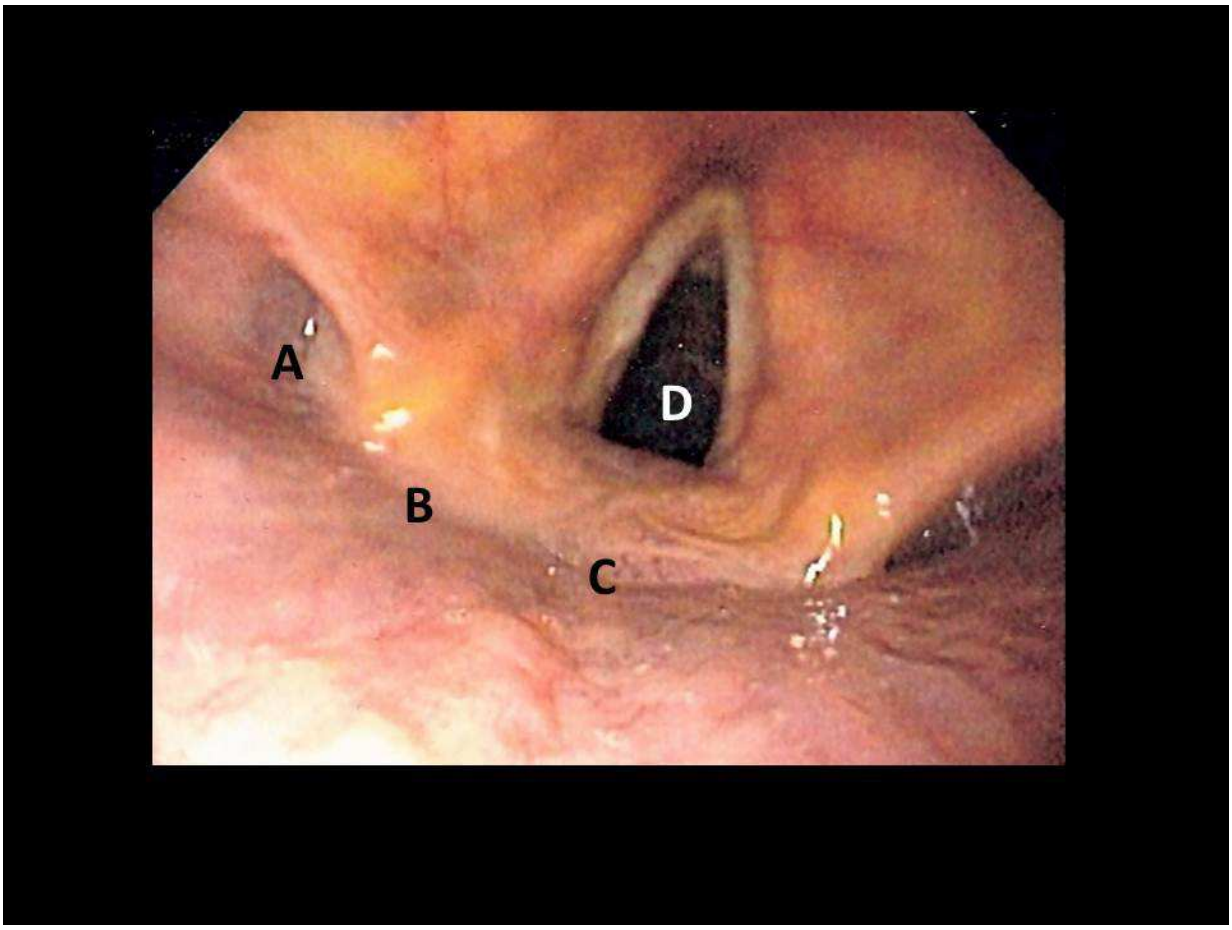
What type of sigmoid colon loop is most beneficial for entry into the descending colon?
Mark only one oval.

- A. Alpha-loop
- B. Reverse alpha-loop
- C. Gamma-loop
- D. N-loop
- E. Reverse-N loop

4. **Question 3 (1 point)**

Below is an endoscopic image of the larynx taken with a gastroscope. Which location is representative of the ideal place to position the gastroscope to intubate the esophagus?
Mark only one oval.

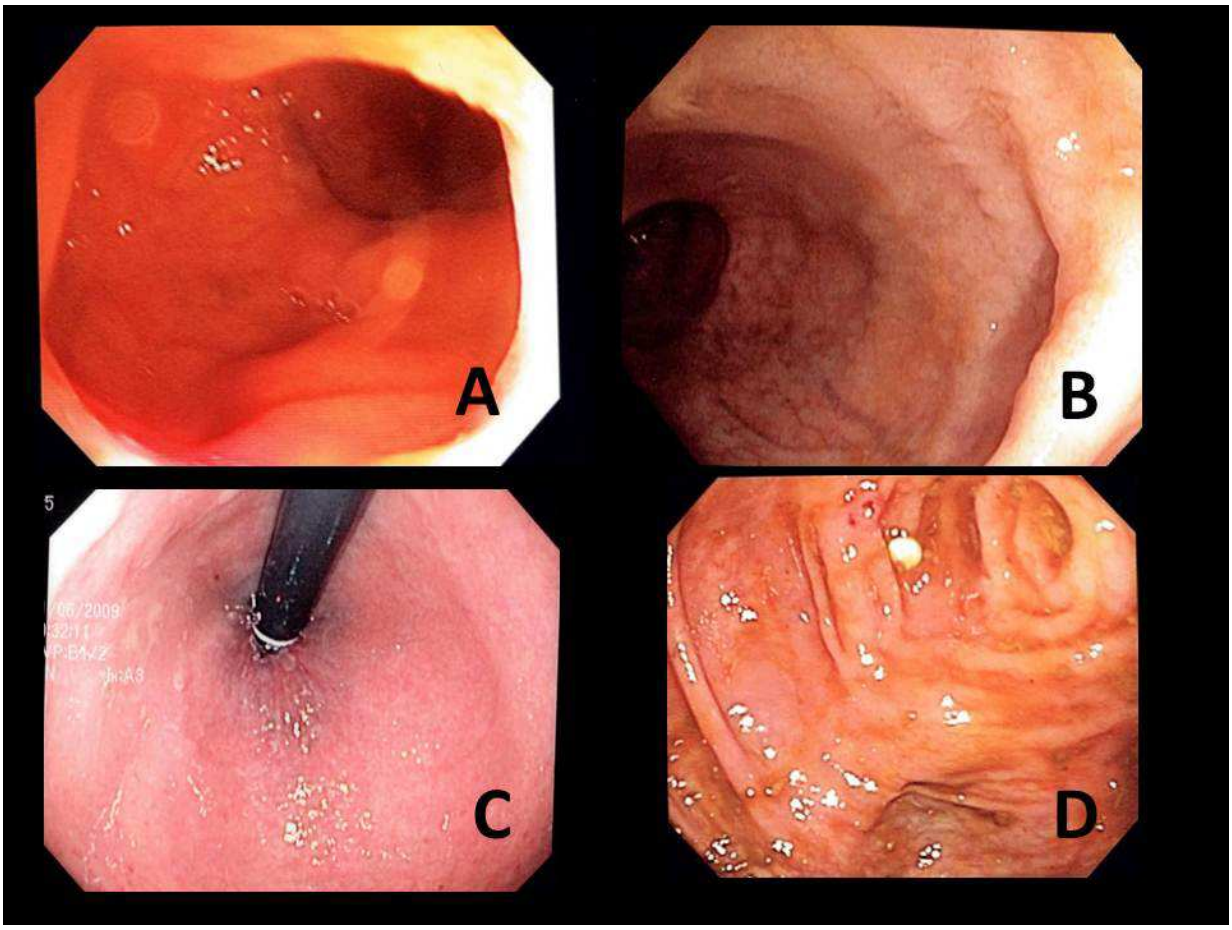
- A
- B
- C
- D



5. **Question 4 (1 point)**

Which of the images below is an endoscopic image of the cecum?
Mark only one oval.

- Image A
- Image B
- Image C
- Image D



6. **Question 5 (1 point)**

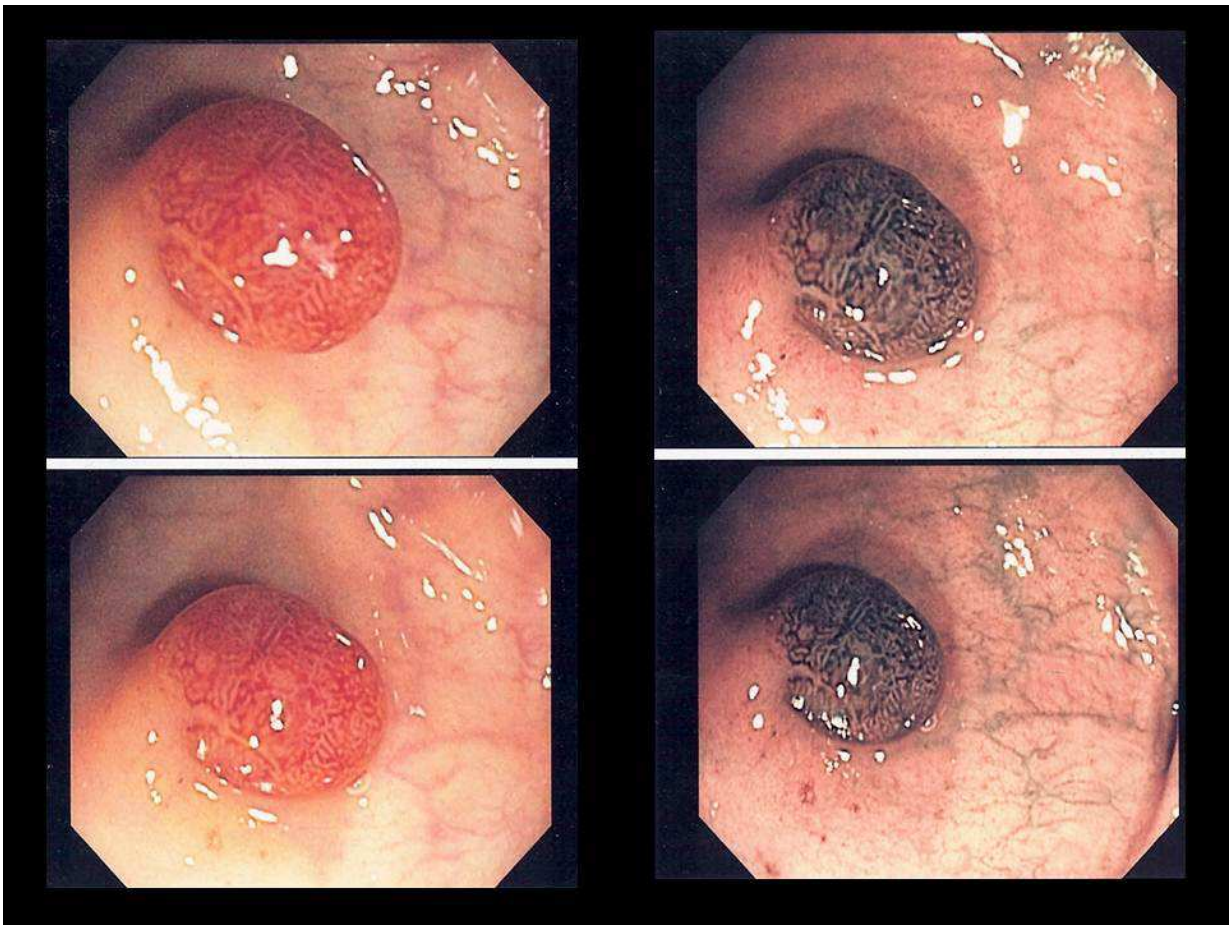
The pit pattern of polyps is commonly used as an endoscopic classification to determine the likely histopathology. What is the name of the classification most commonly used for pit patterns?
Mark only one oval.

- A. Kudo classification
- B. Maclean classification
- C. Yoshida classification
- D. Haggitt classification
- E. Sarin classification

7. **Question 6 (1 point)**

The pit patterns of the polyp depicted below have been enhanced by use of ambient light of blue-green wavelength (approximately 450 - 540 nm). What is the name of this technology?
Mark only one oval.

- A. Confocal microscopy
- B. Optical coherence tomography
- C. Chromoendoscopy
- D. FICE (Fuji intelligent chromoendoscopy)
- E. Narrow band imaging



8. **Question 7 (1 point)**

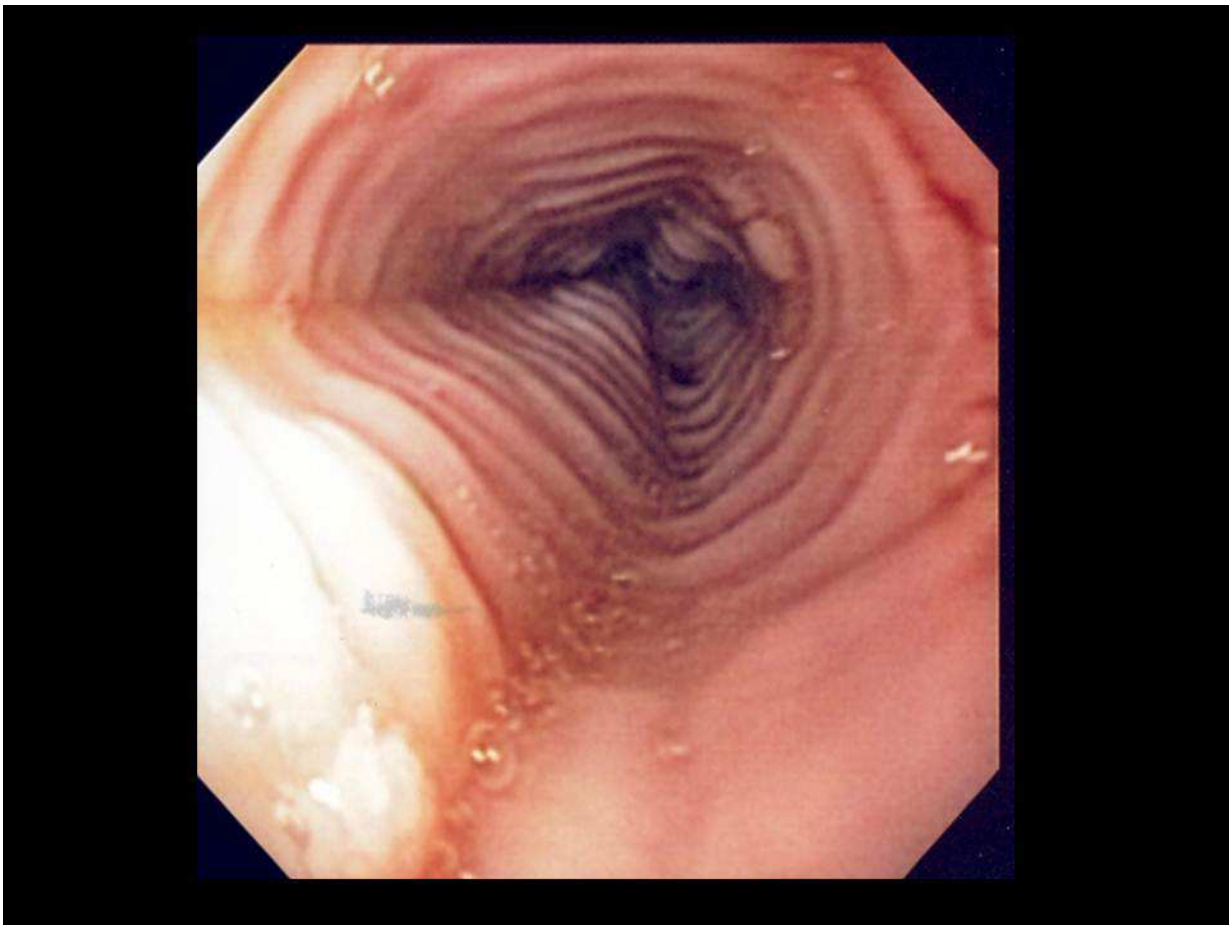
With a well prepared colonoscopy to the cecum performed by an experienced endoscopist, what is the approximate risk of missed advanced neoplasia?
Mark only one oval.

- A. 1%
- B. 3-5%
- C. 5-10%
- D. >10%

9. **Question 8 (1 point)**

Below is an endoscopic view of a patient's esophagus. What is the endoscopic diagnosis?
Mark only one oval.

- A. Eosinophilic esophagitis
- B. Radiation esophagitis
- C. Mosaic esophagus
- D. Barrett's esophagus
- E. Diffuse-type squamous cell carcinoma



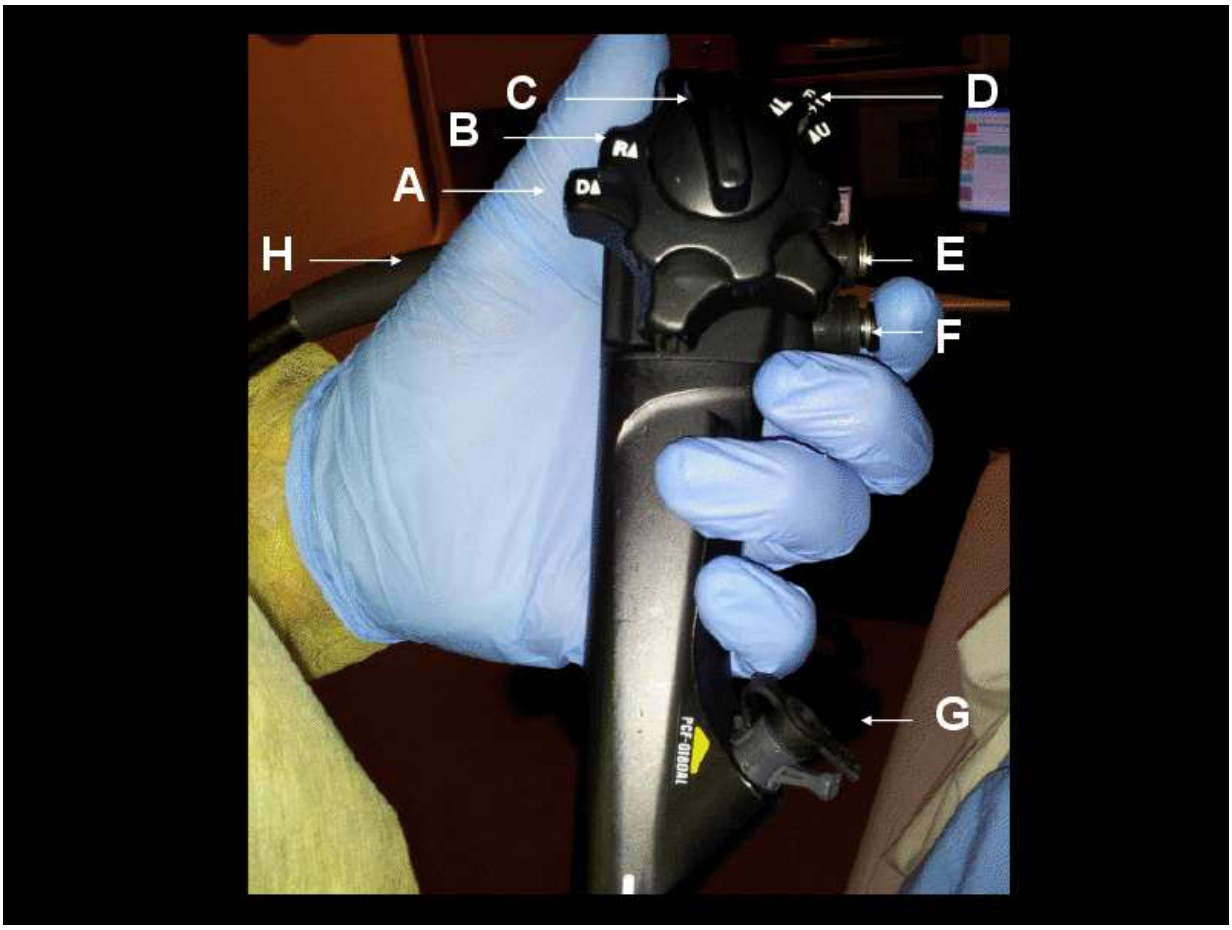
Endoscopy knowledge test (page 2 of 2)

10. **Question 9 (1 point)**

Which of the following is a commonly used bowel preparation score for colonoscopy?
Mark only one oval.

- A. Los Angeles bowel preparation score
- B. Ottawa bowel preparation score
- C. King's College bowel preparation score
- D. Chicago bowel preparation score
- E. Washington bowel preparation score

Question 10 (4 points)



Identify the labelled parts of the colonoscope head (4 points; 0.5 points each)

11. **A**

12. **B**

13. **C**

14. **D**

15. **E**

16. **F**

17. **G**

18. **H**

Question 11 (1 point)

Certain skills necessary for endoscopic performance may be independent of the technical performance of the procedure. Name four non-technical skills that you would view as important in the performance of endoscopic procedures.

19. **A**

20. **B**

21. **C**

22. **D**

23. **Question 12 (1 point)**

Which of the following is not a risk factor for colonic perforation at the time of colonoscopy
Mark only one oval.

- A. Barotrauma
- B. Mucosal injection
- C. Sigmoid looping
- D. Trainee endoscopist performing colonoscopy
- E. Resection of sessile polyp

24. **Question 13 (1 point)**

A 50 year old patient presents for a screening colonoscopy to your open access endoscopy unit. They have completed a 4L bowel preparation. Upon taking a history, you discover that they had a colonoscopy 2 years ago to work up anorectal bleeding but you don't have the results. What is the appropriate course of action?
Mark only one oval.

- A. Complete a screening colonoscopy because the indication of colorectal cancer screening is different than anorectal bleeding.
- B. Another screening colonoscopy is not needed; send patient home.
- C. Make concerted effort to track down report of prior colonoscopy and if not obtained, then proceed with screening colonoscopy.
- D. Make concerted effort to track down report of prior colonoscopy and if not obtained, then explain to patient that they can choose to defer procedure until report is obtained and reviewed
- E. Your endoscopic skills exceed that of the previous endoscopist and the procedure must be repeated.

25. **Question 14 (1 point)**

A unilingual Azerbaijani woman comes in for a gastroscopy to work up epigastric pain. She is unable to understand the consent process, which of the following is most correct?
Mark only one oval.

- A. Do a physical examination; if she has abdominal discomfort, continue with gastroscopy.
- B. Ask the patient's daughter to translate the consent form.
- C. Reschedule the gastroscopy and ask her to bring a translator.
- D. Reschedule the gastroscopy and arrange for a translator to accompany her.
- E. Obtain consent from daughter and proceed with procedure

26. **Question 15 (1 point)**

You are completing a screening colonoscopy and discover a 12 mm pedunculated polyp in the transverse colon. The endoscopy nurse suggests the use of a 10 mm snare and no electrocautery, but you believe a 15 mm snare with electrocautery would be more appropriate. What do you do?
Mark only one oval.

- A. Take the nurse's suggestion since he/she is more experienced than yourself.
- B. Use a 15 mm snare and ignore the nurse.
- C. Ask the nurse for the rationale for the smaller snare and the absence of cautery and verbalize your decision to proceed with the 15 mm snare with cautery.
- D. Discuss with the nurse why you wish to proceed with the larger snare and electrocautery before proceeding with the polypectomy.
- E. Call in a colleague to assist in the decision making.

27. **Question 16 (1 point)**

You are completing a polypectomy of a 2 cm Paris II-a (flat) polyp in the cecum of a 65 year old male. After the polypectomy you notice a perforation in the cecum. You aim to close the defect with endoclips, start antibiotics, and arrange imaging and possible surgery. Which of the following would not be appropriate?
Mark only one oval.

- A. Start the plan above for the management of the patient's complication, as soon as possible.
- B. Inform family members of the procedure's complications before proceeding with the above plan.
- C. Ensure airway, breathing and circulation are intact above all else.
- D. Call for extra assistance into the room as soon as possible.
- E. Stay calm as you manage the situation.

28. **Question 17 (1 point)**

You perform a screening colonoscopy on an anemic 50 year old male who complains of weight loss, altered bowel habits and blood in his stool. You identify the patient is suffering from colorectal cancer. Which one of the following would not be appropriate in explaining the results of the colonoscopy to the patient?
Mark only one oval.

- A. Ensure the results are delivered in a private setting
- B. Do not inform the patient of the suspected diagnosis until you have the pathology results
- C. Ensure to be empathetic during delivery of the results of the colonoscopy
- D. Establish that the patient understands the results after you explain it to them
- E. Be aware of the patient's reaction and tone as you are delivering the news

TEAMSTEPPS TEAMWORK ATTITUDES QUESTIONNAIRE

With respect to how each question applies to interactions with a team in ENDOSCOPY, please respond to the questions below by placing a checkmark in the box that corresponds to your level of agreement from Strongly Disagree to Strongly Agree. We realize that the questions may be a little vague but please select only one response for each question.

Team Structure

29. **1. It is important to ask patients and their families for feedback regarding patient care before/in/after endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

30. **2. Patients are a critical component of the care team in surgery and endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

31. **3. The Department of Surgery or Division of Gastroenterology influences the success of direct care teams in surgery and endoscopy** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

32. **4. In surgery and endoscopy, the mission of the team is of greater value that the goals of individual team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

33. **5. Effective team members can anticipate the needs of other team members** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

34. **6. High-performing teams in health care share common characteristics with high-performing teams in other industries** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Leadership

35. **7. It is important for a surgeon-leader or GI-leader to share information with team members** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

36. **8. Leaders should create informal opportunities for team members to share information** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

37. **9. Effective leaders view honest mistakes as meaningful learning opportunities** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

38. **10. It is a leader's responsibility to model appropriate team behaviour** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

39. **11. It is important for surgeon-leaders or endoscopy-leaders to take time to discuss their team members' plans for each patient** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

40. **12. Team leaders should ensure that team members help each other out when necessary** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Situation monitoring

41. **13. Individuals can be taught how to scan the patient environment in the OR or procedure room for important situation cues.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

42. **14. Monitoring patients provides an important contribution to the effective performance of the team** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

43. **15. Even individuals who are not part of the direct care team should be encouraged to scan for and report changes in patient status** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

44. **16. It is important to monitor the emotional and physical status of other team members** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

45. **17. It is appropriate for one team member to offer assistance to another who may be too tired or stressed to perform a task** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

46. **18. Team members who monitor their emotional and physical status on the job are more effective** *
Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Mutual support

47. **19. To be effective, team members should understand the work of their fellow team members.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

48. **20. Asking for assistance from a team member us a sign that that individual does not know how to do his/her job effectively** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

49. **21. Providing assistance to team members is a sign that an individual does not have enough work to do** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

50. **22. Offering to help a fellow team member with his/her individual work tasks is an effective tool for improving team performance** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

51. **23. It is appropriate to continue to assert a patient safety concern until you are certain that it has been heard.** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

52. **24. Personal conflicts between team members do not affect patient safety** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

Communication

53. **25. Teams that do not communicate effectively significantly increase their risk of committing errors** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

54. **26. Poor communication is the most common cause of reported errors** *

Mark only one oval.

- Strong disagree
- Disagree
- Neutral
- Agree
- Strongly agree

55. **27. Adverse events may be reduced by maintaining an information exchange with patients and their families** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

56. **28. I prefer to work with team members who ask questions about information I provide** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

57. **29. It is important to have a standardized method for sharing information when handing off patients after endoscopy** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

58. **30. It is nearly impossible to train individuals how to be better communicators** *

Mark only one oval.

- ◯ Strong disagree
- ◯ Disagree
- ◯ Neutral
- ◯ Agree
- ◯ Strongly agree

59. **Please indicate any additional comments in the space below.**

Thanks for your participation.

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Endoscopist Participant ID #: _____ Date (DD/MM/YYYY): _____ Start Time: _____

End Time: _____

Assessor: Self-Assessment VR Simulator (circle one): 1 2 3

VR Case: _____

ENDOSCOPIC NON-TECHNICAL SKILLS SELF-REFLECTION TOOL

	Y / N
1. Did I take a focused patient history?	
2. Did I review the patient's medications (i.e. anticoagulants) and allergies?	
3. Did I identify the correct procedure and take an appropriate consent?	
4. Did I discuss the sedation plan with the anesthetist or RN?	
5. Did I introduce the team and myself to the patient?	
6. Did I discuss the procedure with the patient and address concerns?	
7. Did I ask the team if they were ready to start?	
8. Did I situate the patient in the correct position?	
9. Did I verbalize/acknowledge relevant anatomy/landmarks?	
10. Did I check vital signs often (every few minutes)?	
11. Did I update the team and patient on the progress of the procedure?	
12. Did I address patient comfort (i.e. ask the patient where pain is) and enact a plan for a patient who was not comfortable?	
13. Did a secondary goal arise during the procedure (e.g. polypectomy)? Did I identify issues and problems that arose from this scenario? Did I verbalize the plan to attend to these?	
14. Did I use closed-loop communication when interacting with the team?	
15. Did I discuss results with the patient post-procedure (i.e. complication, what was found, etc.) and create a follow-up plan?	
16. Was I respectful toward the patient and team?	
17. Did I identify any errors I made afterward? If so what can I do to improve my performance?	


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M-OSANTS – NON-TECHNICAL SKILLS

SITUATIONAL AWARENESS: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to remain aware of the patient's history (e.g. allergies, medications, etc.)? Did the endoscopist review procedural details prior to procedure (e.g. confirms correct procedure)? Did the endoscopist demonstrate procedural planning (e.g. identifies objectives for the procedure at the start)? Did the endoscopist collect and use information during the procedure (e.g. change in vital signs)? Did the endoscopist recognize the scope of practice (e.g. refrain from unfamiliar procedures/ interventions)? Did the endoscopist anticipate potential problems during the procedure while proposing suitable solutions (e.g. proactively apply loop reduction strategies)? Was the endoscopist mindful of procedure time? Did the endoscopist ensure that patient outcomes are met (e.g. maintain patient comfort)? Did the endoscopist anticipate needs of team members and of the patient (e.g. minimize patient anxiety)?				

DECISION MAKING: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to implement endoscopic and clinical knowledge when making a decision (e.g. choosing equipment appropriate to endoscopic appearance)? Did the endoscopist identify issues and subsequently tailor a plan for resolution (e.g. application of loop reduction strategies)? Did the endoscopist confidently create a plan and articulate details of the plan to the team)? Did the endoscopist demonstrate understanding of the risks and benefits of an intervention/ maneuver (e.g. aware of bleeding risk due to polypectomy)? Did the endoscopist account for relevant patient information (e.g. mindful of contraindications)? Did the endoscopist appropriately delegate tasks to staff (e.g. requesting equipment from nurses)? Did the endoscopist enact a subsequent option if initial action unsuccessful? Did the endoscopist respond appropriately if the procedure extends out of the endoscopist's scope of practice (e.g. asking for assistance from senior staff)?				

COMMUNICATION: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to receive and respond to information from team members? Did the endoscopist actively limit distractions in the room (e.g. restricts cell phone use)? Did the endoscopist convey information using a closed-loop (e.g. confirms amount of sedation to be administered)? Did the endoscopist speak with clarity, while providing details when appropriate (e.g. requesting snare with specific size)? Did the endoscopist indicate a specific team member if there are multiple staff (e.g. addresses nurse by name)? Did the endoscopist use language appropriate for the recipient (e.g. minimizes medical jargon for patients)? Was the endoscopist aware of verbal tone and volume (e.g. speaks to staff in a respectful, collegial manner that can be heard)? Did the endoscopist ensure that the recipient understands information (e.g. patient comprehends risks)? Did the endoscopist relay findings to patient, including any adverse events (e.g. follow-up during aftercare)?				

LEADERSHIP: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to take responsibility for the process of the procedure (e.g. acknowledge mistakes)? Did the endoscopist direct the flow of the team process, including an appropriate delegation of labour (e.g. requesting that nurses attend to patient discomfort)? Did the endoscopist demonstrate confidence when leading the team, even under pressure (e.g. maintains composure during a bleed)? Did the endoscopist lead the endoscopic pause?				

PROFESSIONALISM: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Did the endoscopist demonstrate a respectful and courteous attitude towards the patient and team members (e.g. introduces himself/herself to everyone in the room)? Did the endoscopist acknowledge mistakes during procedure? Did the endoscopist display empathy for the patient (e.g. responds to patient discomfort)? Did he endoscopist advocate on behalf of the patient? Did the endoscopist manage time appropriately (e.g. mindful of endoscopy unit time)? Did the endoscopist ensure follow-up and address patient concerns within appropriate environment (e.g. follow-up within office or dedicated clinical area)? Did the endoscopist refrain from inappropriate conversations (e.g. does not discuss other patients during a procedure)? Did the endoscopist ensure that the procedure adheres to best-practice guidelines (e.g. record quality metrics)?				

TEAMWORK: sample questions are listed below, give a global rating.				
1 - Fail	**2 - Poor**	**3 - Average**	**4 - Very good**	**5 - Excellent**
Was the endoscopist able to act effectively within the team of nurses, technicians, management, and other physicians? Did the endoscopist demonstrate respect for all members of the team (e.g. speaks in a collegial, respectful tone)? Was the endoscopist aware of the roles of all members of the endoscopic team? Did the endoscopist display willingness to assist others, if appropriate (e.g. when transferring a patient)? Did the endoscopist ask for advice from other team members? Did the endoscopist take into account feedback from other team members (e.g. listens to suggestions for equipment)?				

Endoscopist Participant ID #: _____ Date (DD/MM/YYYY): _____ Start Time: _____

End Time: _____

Assessor: _____ VR Simulator (circle one): 1 2 3

VR Case: Polypectomy Case 3

Maximal distance reached (check one):

- ☐ Rectum
- ☐ Sigmoid
- ☐ Descending Colon
- ☐ Splenic Flexure
- ☐ Hepatic Flexure
- ☐ Ascending Colon
- ☐ Cecum
- ☐ Terminal Ileum

DOPS – TECHNICAL SKILLS

Please write the appropriate score from the scale below

Scale:
4 Highly skilled performance
3 Competent & safe throughout procedure, no uncorrected errors
2 Some standards not yet met, aspects to be improved, some errors uncorrected
1 Accepted standards not yet met, frequent errors uncorrected

CRITERIA	SCORE
Assessment, consent, communication	
• Obtains informed consent using a structured approach ○ Satisfactory procedural information ○ Risk and complications explained ○ Co-morbidity ○ Sedation ○ Opportunity for questions	**1 2 3 4**
• Demonstrates respect for patient's views and dignity during the procedure	**1 2 3 4**
• Communicates clearly with patient, including outcome of procedure with appropriate management and follow up plan. Full endoscopy report.	**1 2 3 4**
Safety and sedation	
• Safe and secure IV access (or indicates need)	**1 2 3 4**
• Gives appropriate dose of analgesia and sedation and ensures adequate oxygenation and monitoring of patient (or indicates does, need for monitoring)	**1 2 3 4**
• Demonstrates good communication with the nursing staff, including dosages and vital signs	**1 2 3 4**
Endoscopic skills	
○ Checks endoscope function before intubation (or indicates need to check)	**1 2 3 4**
○ Performs/Indicates need for PR	**1 2 3 4**
• Maintains luminal view / inserts in luminal direction	**1 2 3 4**
• Demonstrates awareness of patient's consciousness and pain during the procedure and takes appropriate action	**1 2 3 4**
○ Uses torque steering and control knobs appropriately	**1 2 3 4**
○ Uses distension, suction and lens washing appropriately	**1 2 3 4**
• Recognizes and logically resolves loop formation	**1 2 3 4**
○ Uses position change and abdominal pressure to aid luminal views	**1 2 3 4**
○ Completes procedure in reasonable time	**1 2 3 4**
Diagnostic and therapeutic ability	
• Adequate mucosal visualization	**1 2 3 4**
• Recognizes caecal/desc. colon landmarks or incomplete examination	**1 2 3 4**
• Accurate identification and management of pathology	**1 2 3 4**
• Uses diathermy and therapeutic techniques appropriately and safely	**1 2 3 4** ☐ **N/A**
• Recognizes and manages complications appropriately	**1 2 3 4** ☐ **N/A**

Appendix X: Badge Table

Requirement Needed	Standardized Hints	Setting	Hour
Complete a case in less than a minute	Complete a case in less than a minute	Low fidelity	Hour 1
Complete Low Fidelity	Complete all Low fidelity cases	Low Fidelity	Hour 1
Proper Torque (as determined by assessor)	Torque properly	Low Fidelity	Hour 1
Less than 10% time in red-out	Be careful how much time in red out you spend.	Intro 3/4	Hour 2
Less than 90% Air left in colon	Remove an appropriate amount of air from the colon	Intro 3/4	Hour 2
Over 90% visualization	Make sure to have enough visualize the colon	Intro ¾	Hour 2
Identify the Ulcerative Colitis	ID a diagnosis	Intro 5	Hour 3
Identify pseudomembranous colitis	ID a diagnosis	Biopsy 3	Hour 3
Successful biopsy of Crohn's patient	Use the biopsy forceps	Poly 4	Hour 3 or 4
Take a Photo of a Pedunculated Polyp	Take photos	Poly 1	Hour 4
Identification of location of Polyp (splenic flexure or _cm in)	Say what you see	Poly 3	Hour 4
Outline major risks in colonoscopy Minimum of 4/5 1. Infection 2. Perforation 3. Missed lesions 4. Sedation complications 5. Bleeding	Pros and Cons	Integrated Scenarios	Hour 5/6
Pain acknowledgement (administration of meds, empathetic statement)	"Pain"	Integrated Scenarios	Hour 5/6

No time in extreme Pain	Patient comfort is important	Integrated Scenarios	Hour 5/6
Do an endoscopic Pause 1. Indicate a pause 2. Revise case 3. Feedback from SN	“Pause”	Integrated Scenarios	Hour 5/6
Retroflex without assistance	“Rectum”	High Fidelity	Any
Intubate the TI	Make sure you finish the whole pathway	High Fidelity	Any

Assessors please fill out

NURSE ASSESSED PATIENT COMFORT SCORE (NAPCOMS)

Domain	Item	0	1	2	3	Score
Pain	1- Intensity	None or minimal	Mild	Moderate	Severe	
	2- Frequency	None	Few (1 or 2 episodes)	Several times (3-4 episodes)	Frequent (>4 episodes)	
	3- Duration	None	Short duration (episode <30 seconds)	Moderate duration (30 sec-1 minute)	Long duration (episode lasts >1 min)	
	Total Pain Score (Intensity + Frequency + Duration)					
Sedation	Level of consciousness*	Alert	Sleepy but initiates conversation	Responds only when asked or stimulated	Unresponsive or only responds with pronounced simulation	
Global	Tolerability*	Very well tolerated	Reasonably well tolerated	Just tolerated	Poorly tolerated	

*Note: level of consciousness and tolerability are not used in overall score

Cognitive Load Index for Colonoscopy

CRITERIA	SCORE
Intrinsic load items: Please rate your agreement with the following statements regarding the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. Physically manipulating and controlling the colonoscope was difficult	**0 1 2 3 4 5 6 7 8 9 10**
2. Using ancillary instruments (i.e. biopsy forceps, polypectomy snare) was difficult	**0 1 2 3 4 5 6 7 8 9 10**
3. Identifying normal anatomy and/or landmarks was difficult	**0 1 2 3 4 5 6 7 8 9 10**
4. The endoscopic findings were complex or difficult to characterize	**0 1 2 3 4 5 6 7 8 9 10**
5. It was difficult to manage identified pathology (i.e. polyps that were difficult to remove, bleeding that was difficult to control)	**0 1 2 3 4 5 6 7 8 9 10**
6. It was difficult to keep track of, or remember, all the endoscopic findings	**0 1 2 3 4 5 6 7 8 9 10**
7. Managing the patient's level of comfort was difficult	**0 1 2 3 4 5 6 7 8 9 10**
8. Overall, this colonoscopy was difficult and/or complex	**0 1 2 3 4 5 6 7 8 9 10**
Extraneous load items: Please rate your agreement with the following statements regarding your experience during the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. My supervisor's instructions were unclear	**0 1 2 3 4 5 6 7 8 9 10**
2. My supervisor used language that was confusing or unfamiliar	**0 1 2 3 4 5 6 7 8 9 10**
3. The manner in which my superior provided instructions	**0 1 2 3 4 5 6 7 8 9 10**
4. I felt distracted by other people present in the endoscopy room	**0 1 2 3 4 5 6 7 8 9 10**
5. I felt distracted by the environment (i.e. my pager going off, environmental noise)	**0 1 2 3 4 5 6 7 8 9 10**
6. I felt distracted by things on my mind unrelated to this colonoscopy	**0 1 2 3 4 5 6 7 8 9 10**
Germane load items: Please rate your agreement with the following statements regarding your level of mental effort during the colonoscopy you've just completed. Please circle from 0 (strongly disagree) to 10 (strongly agree)	
1. I invested substantial mental effort learning how to control or manipulate the colonoscope and/or other endoscopic equipment	**0 1 2 3 4 5 6 7 8 9 10**
2. I invested substantial mental effort identifying or understanding colonic anatomy	**0 1 2 3 4 5 6 7 8 9 10**
3. I invested substantial mental effort understanding, remembering and/or managing the endoscopic findings	**0 1 2 3 4 5 6 7 8 9 10**
4. I invested substantial mental effort learning how to manage patient comfort level	**0 1 2 3 4 5 6 7 8 9 10**
5. Overall, I invested substantial mental effort learning during this colonoscopy	**0 1 2 3 4 5 6 7 8 9 10**

St. Michael's

Inspired Care. Inspiring Science.

Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

This is a consent form regarding the above mentioned research study. Before you give your consent to voluntarily participate in this study, it is important that you read the following information and ask the study personnel as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

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Background and Purpose of the Study

Colonoscopies are medical procedures that gastroenterology physicians and general surgeons learn during their residency training. Traditionally, these procedures are learned for the first time on patients in the clinical setting under the supervision of a fully-trained attending physician. Virtual reality (VR) has since been used to create devices, called endoscopic simulators that can emulate the look and feel of performing colonoscopies, and have been validated in research studies to confer basic skills to trainees. The optimal method to use virtual reality simulators for teaching trainees that have yet to begin procedures in colonoscopy has yet to be determined, and was identified by the American Society for Gastrointestinal Endoscopy as a need for further training.

The primary objective of this project is to evaluate the impact of a simulation-based training curriculum using gamification on clinical performance in colonoscopy.

Eligibility

You are asked to consider taking part in this study if you are a resident in General Surgery, Adult Gastroenterology or Pediatric Gastroenterology at the University of Toronto.

In order to be eligible for this study, you must be a post-graduate trainee in the above programs, must have completed less than 25 colonoscopic procedures, and must have completed less than 25 simulated colonoscopy procedures to date.

Description of the Study

We aim to recruit 36 postgraduate novice endoscopists from the Adult Gastroenterology, Pediatric Gastroenterology and General Surgery training programs at the University of Toronto. **Note:** this study takes place concurrently alongside the Annual Endoscopic Simulation Training Course. The study, as described below, is a randomized control trial that is investigating the effectiveness of a new simulation-based curriculum. The Annual Endoscopic Simulation Training Course is an educational program through the University of Toronto, which aims to teach novices how to perform colonoscopies. Participation in the study component is optional; if you chose to opt-out of the study, it will not impact your participation in the course.

You will be asked to take a written questionnaire at the start of the study to collect demographic and background information including: age, sex, level of training, previous endoscopy experience and nature of experience, and video game experience, which may correlate with baseline endoscopic skill.

Following this you will take part in a pre-test consisting of the following:

1. **Knowledge Test:** A 30 minute (17 questions) multiple-choice question test designed to assess participants' theoretical knowledge of colonoscopy, including indications, sedation, safety, findings, pathology and follow-up.

2. VR Simulation Test: This test will assess baseline endoscopic technical proficiency through the completion of a colonoscopy procedure on the VR simulator (EndoVR® Colonoscopy Module 3). This scenario simulates a screening colonoscopy, without the need for any type of intervention (such as biopsy). The time limit of the procedure will be 30 minutes. An expert rater will be present to assess performance, but will not provide assistance. You will be videotaped in order to obtain performance measures, such that your faces are not captured (to ensure anonymity). Prior to starting the procedure, you will complete a questionnaire to measure self-efficacy.

3. VR Simulation Based "Integrated Scenario" Test: Following the simulator-only test, participants will complete an Integrated Scenario format test to assess their baseline endoscopic non-technical proficiency. This simulated procedure will mimic the setup of an endoscopic suite, as the VR simulator will be positioned next to a patient bed. A standardized patient, who will receive instructions regarding their medical role, will act out a scenario on colon cancer screening. You will be expected to explain the colonoscopy procedure, its benefits and risks, and to obtain procedural consent. You will then carry out the procedure on the VR simulator (EndoVR® Polypectomy Module #3) while responding to the patient and interacting with the standardized nurse (SN) as appropriate. The Standardized Patient (SP) will act out cues from the VR simulator if the simulator signals that the procedure has exceeded its threshold for discomfort. Your performance will be videotaped (in a manner that their faces are not captured to ensure anonymity) in order to obtain performance measures. You will be given a maximum of 45 minutes to complete the procedure.

You will then be randomized, using an online randomization algorithm, to one of two groups:

1. Control Group: This group will receive 4 hours of interactive small-group didactic and hands-on sessions. During these sessions, participants will focus on learning about the theory of colonoscopy, including related concepts of pathology, anatomy, and therapeutic technique. The last session will focus on non-technical skills (NTS) relevant to endoscopy (situation awareness, decision making, communication, teamwork, and leadership) and how they relate to clinical performance. During this session, participants will also watch a video that demonstrates an ideal endoscopic procedure in terms of NTS, as well as learn about the "E-NTS Checklist", which will be provided for them to later use during the integrated scenario training. This checklist has been developed according to evidence-based recommendations and targets non-technical skills. After each didactic session, a short MCQ based on the topics covered in that session will be administered, in keeping with suggestions from the literature regarding "test-enhanced learning". In addition to didactic training, the control group will be given six hours of expert-assisted instruction on both the low-fidelity simulator (1 hour) and on the high-fidelity VR simulator (5 hours). Six modules of increasing difficulty in colonoscopy and colonoscopic polypectomy will be taught using one-on-one feedback from an expert academic endoscopist. The endoscopy instructor will demonstrate techniques, answer

questions and provide individualized performance feedback on global performance, with a focus on non-technical skills. During training on the high-fidelity simulator, the last two hours will take the form of the integrated scenario, which will feature a standardized patient (SP) and standardized nurse (SN). Terminal feedback will be given after each integrated scenario by the instructor. Finally, the "E-NTS Checklist" will be accessible during training in the integrated scenario, as participants can view the checklist prior to each case and review it after the case.

2. Intervention Group: This group will receive the same 4 hours of didactic teaching, and hands-on sessions. The intervention group will also receive the same teaching on both the low-fidelity and high-fidelity simulators. Within the context of the didactic sessions and simulator training, the GIC group will engaged in "gamified practice" in two ways. First, leaderboards will also be used to track and rank participants' performances. Prior to training, participants in the GIC group will watch a tutorial video on the functionality of the leaderboards and subsequently receive an anonymized ID tag that can be used to identify only their position on the leaderboard. Participants will also be informed that awards will be given to the individual who achieves first place. An "introductory" leaderboard, based on technical skills performance during the low-fidelity simulator practice, will be used to familiarize participants with the function of the leaderboard. After practice on the low-fidelity simulator is completed, participants will be introduced to the leaderboard for performance on the VR simulator and didactic sessions. Specifically, this leaderboard will include 4 components: a non-technical skills score, a technical skills score, a cognitive skills score,and an overall ranking, which will be determined through an algorithm that accounts for non-technical, technical and cognitive scores. Scoring of the non-technical and technical skills will be based on assessed performances during practice sessions on the VR simulator using the M-OSANTS and JAG-DOPS, respectively, while the scoring of the cognitive skills will be based on percentage scores of the MCQ from the didactic sessions. Scores will be aggregated only from participants training on the same days. The leaderboard will be displayed on a central laptop and/or TV screen and will be accessible at any time throughout the day. Finally, participants in the GIC group will have the opportunity to be rewarded for their performances. One method of reinforcing good performance will be through achievement badges. These badges will be awarded after each scenario on the high-fidelity simulator and will be based on completion, proper technique, and/ or correct identification of pathology. Additionally, the participant who has accumulated the most badges will be awarded a prize.

A post-test will be administered after completion of the training period to compare learning between the two groups, consisting of:

1. Knowledge Test

Knowledge acquisition will be evaluated using a 30 minute (17 questions) multiple-choice question test designed to assess theoretical knowledge of colonoscopy.

2. Simulation-based Assessment

You will be assessed through the completion of a colonoscopy procedure on the VR simulator. As with the pre-test, the post-test will include an "integrated scenario" which links a standardized patient with the VR colonoscopy simulator. You will once again be required to explain the procedure, its benefits and risks, and obtain informed consent. You will then carry out the procedure on the simulator while responding to the patient as appropriate. Once again, the performance of all participants will be videotaped, such that their faces are not captured to ensure anonymity, in order to obtain performance measures.

3. Patient-based transfer test

You will then be contacted to undertake two colonoscopies on real patients. These procedures will be videotaped in a manner that anonymizes you and the patient. The videotapes will be assessed by two independent blinded expert endoscopists.

Potential Harms (Injury/Discomfort/Inconvenience)

There are no known harms associated with participation in this study.

Potential Benefits

You will not receive credit in performing colonoscopies by participating in this study. You may receive no direct benefits from being in this study. Results from this study will be used to adjust the structure and format of the current University of Toronto virtual-reality colonoscopy training curriculum for novice endoscopic trainees.

Confidentiality and Privacy

All the persons associated with this study, including the study investigators and delegates (study team) are committed to respecting your privacy. No information that discloses your identity will be published or released to any other persons without your consent unless required by law.

Video-recordings of your face are considered to be identifying personal information and will not be shown when videotaping these procedures. During the video-recordings, you are requested not to state your name or the names of anyone else or any institutions. However if this does happen, you should know that the audio track from the video will be removed so identifying information is removed.

Any records, documentation, or information related to you will be coded by study numbers to ensure that persons outside of the study will not be able to identify you. All study data forms will be identified by study code number and not by name. No identifying information about you will be allowed off site. All information that identifies you and study data will be securely stored at St. Michael's Hospital. The video recordings will be securely destroyed after data collection. Other identifying information will be securely destroyed after all the colonoscopy procedures have been completed. The study

data will be securely destroyed when the study results have been published, within five years after completion of the study.

It is important to understand that despite these protections being in place, experience in similar studies indicates that there is the risk of unintentional release of information. The principal investigator and study personnel will protect your records and keep all the information in your study file confidential to the greatest extent possible. The chance that this information will accidentally be given to someone else is minimal.

Data collected during this study will not form any part of your evaluation for the rotation and will not be forwarded to your program director or any other individual involved in your evaluation in residency. The study investigators will have access to the coded study data, but will not have access to your identifying information, including the video-recordings. The St. Michael's Hospital Research Ethics Board may have access to your identifying information and study data collected, for the purpose of study monitoring.

In no way does signing this consent form waive your legal rights nor release the investigators or involved institution from their legal and professional responsibilities.

Voluntary Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw or are withdrawn from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Study Results

We may present this study at a scientific conference and we intend to write an article about this study for a scientific journal. No identifying information about you will be revealed in any presentation or publication about the study. Study results will be communicated to you by request following completion of the study. You can ask for a copy of the published article by contacting Michael Scaffidi, Research Assistant, at (416) 864-5628 or by e-mail at scaffidim@smh.ca.

Potential Costs of Participant and Reimbursement to the Participant

Participating in this study will not result in any costs charged to you, and as such, no reimbursements or compensation will be provided.

Sponsor

This study is funded by a grant from the University of Toronto.

Compensation for Injury

If you suffer a physical injury from (the procedure(s) or participation) in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study doctor(s), sponsors or involved institutions from their legal and professional responsibilities.

Participation and Withdrawal

Participation in this study is voluntary. You are free to decline participation in this study and to withdraw from the study at any time if you so desire. Whether you participate in this study or not, it will not have any effect on your participation in the Annual Endoscopic Simulation Course, clinical evaluations, or standing in your academic program at the University of Toronto, nor will it in any way affect your admission to (or current status in) a residency/fellowship program, nor your current or future employment at St. Michael's Hospital. If you withdraw from the study, information gathered from you up to that point will be kept and used in the study, unless you request that it not be used, and we are able to remove it.

Can Participation in this Study End Early?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact the Research Coordinator, Michael Scaffidi, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions

Research Ethics Board Contact

If you have any questions regarding your rights as a research participant, you may contact the Chair of the Research Ethics Board, St. Michael's Hospital at 416-864-6060 ext. 2557 during regular business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

Study Contacts

If you require further information, or have any questions concerning this study, please contact the principal investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Collect calls will be accepted.

You may also contact the research assistant, Michael Scaffidi, at (416)-864-5628 or by e-mail at scaffidim@smh.ca.

You will be given a copy of this consent form to keep for your own records.

Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

Principal Investigator
Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

Declaration of Consent

The research study has been explained to me, and any questions that I have asked about the study have been answered to my satisfaction. A member of the study team, who has no influence on my academic program, will be obtaining my consent form. I have the right not to participate and the right to withdraw from this study without affecting my participation in the Annual Endoscopic Simulation Course, evaluation or standing on my academic program at the University of Toronto, or any admission to (or current status in) a residency/fellowship program. I have also been informed that my choice will not affect my current or future employment at St. Michael's Hospital. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators or involved institution from their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that records relating to me in this study will be kept confidential and that no information will be released or printed that would disclose my personal identity without my permission unless required by law. I have been given sufficient time to read the above information. I consent to participate in this study. I will be given a signed copy of this consent form.

Name of Participant (print)	Signature	Date

I have explained the study to the above-named participant and discussed the potential risks and benefits (if any) associated with participation in this research study. I have answered all questions asked with respect to this research study.

Name and Position of Person Conducting Consent Discussion (print)	Signature of Person Consent Discussion	Date

St. Michael's
Inspired Care. Inspiring Science.

Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY
Patient participants

This is a consent form regarding the above mentioned research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Before you give your consent to be a volunteer, it is important that you read the following information and ask as many questions as necessary to be sure you understand what you will be asked to do.

Investigators

Principal Investigator:

Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology
St. Michael's Hospital
16-036 Cardinal Carter Wing
30 Bond Street
Toronto, Ontario M5B 1W8
Phone: (416) 864-5628 Fax: (416) 864-5882
E-mail: grovers@smh.ca

CONFLICTS OF INTEREST
We have no known actual, apparent, potential or perceived conflicts of interest in conducting this study.

FUNDING SOURCE

This study is funded by a grant provided by the University of Toronto, Division of Gastroenterology.

PURPOSE OF THE RESEARCH
You are being asked to consider participating in this study because you are booked to have a colonoscopy.

Colonoscopy is a technically challenging procedure and it requires considerable training to learn the skill. Increasingly trainees that learn these skills are learning them on high-fidelity virtual reality simulators that have been designed to teach colonoscopy, prior to performance on real patients. Although simulation-based practice is being integrated into endoscopy training curricula, there is no consensus on the best way to how to do this. One method that has been used in surgical simulation is to interlace a lecture-based curriculum with supervised procedures with feedback with experts. It is unknown whether this provides better learning than self-directed endoscopic procedural learning.

The purpose of this study is to compare performance on colonoscopies performed on a virtual reality endoscopic simulator between two groups of beginning endoscopists, one trained with a curriculum that using gamficiation and one trained with a curriculum that uses conventional simulationtraining.

DESCRIPTION OF THE RESEARCH

WHAT WILL HAPPEN DURING THIS STUDY?

Two physician assessors will be asked to evaluate the performance of the physician performing your colonoscopy. In order to assess the performance, videotaping is required. The physicians will use standardized tests for performance of colonoscopy in order to perform the assessment. To ensure anonymity, your face and the endoscopist's face will not be recorded. Two views of the procedure will be captured at the same time: 1) a close-up view of the endoscopist's gloved hands using the control knobs and tube of the colonoscope and 2) the view obtained by the colonoscope's camera which shows the inside of the your bowel.

You will be asked, in person, to provide some personal health information including your age, gender, the reason why you having the colonoscopy procedure and if you have any history of a difficult colonoscopy or if you have had surgery in the past to remove part of your bowel.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

It is anticipated that about 120 people (80 patients and 40 endoscopists) will participate in this study at St. Michael's Hospital. The study is expected to take three years to complete.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

All data will be collected during your scheduled colonoscopy procedure time. Participation in this study will take no additional time and the duration of your colonoscopy procedure itself will not be affected.

If you decide to participate in this study you will be asked to do the following:

(1) Provide one of the study investigators, in person, with some personal health information including your age, gender, the reason why you are having the colonoscopy procedure and if you have any history of a difficult colonoscopy or have had surgery in the past to remove part of their bowel.

(2) Agree to allow your colonoscopy procedure to be videotaped during this study. Your name and face will not be shown to the camera.

POTENTIAL HARMS (Injury, discomfort, inconvenience)

You may experience side effects from participating in this study. Some of these risks we know about. There is also the possibility of risk that we do not know about or have not seen in study subjects to date. Some of these can be managed. If you decide to take part in this study, you should contact Dr. Samir C. Grover (Division of Gastroenterology, St. Michael's Hospital, 416-864-5628) if you think you have side effects even if you think it has nothing to do with the study.

The risks we know of are:

There are no direct short- or long-term risks anticipated. Data collected will be kept completely confidential and anonymous. Even though the risk that a participant's data could become public is very small, it can never be completely eliminated. However, every precaution is taken to prevent this. Any data collected during the study (e.g. performance assessments, videotaped performance) will be identified using only an individualized number known only to the principal investigator (Drs. Grover) so that your privacy is protected.

POTENTIAL BENEFITS

There is no benefit to you from your participation in this study.

PROTECTING YOUR INFORMATION

You have the right to have any information about you that is collected, used or disclosed for this research study to be handled in a confidential manner. No information that discloses your identity may be released or published without your consent. All information obtained during the study will be held in strict confidence. Even though the risk that your data could become public is very small, it can never be completely eliminated. However, every precaution is taken to prevent this. Prior to starting the study, you will be assigned a unique code known only to the principal investigator (Dr. Grover) so that your privacy is protected. Any data collected during the study will be identified using only this code.

The file which links your unique study identifier with your name is the only source of information that could possibly be utilized, either alone or with other information, to identify you. This encrypted file will be kept behind locked doors in Dr. Samir Grover's office, St. Michael's Hospital until data analysis is complete (anticipated time frame: 5 years). After that time it will be securely destroyed as per hospital requirements. Only Dr. Grover (principal investigator) will have access to this file.

Any study data about you that is sent outside of the hospital will be aggregate data for research presentations and publications. No individual level data will be reported .

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, including personal health information, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated. Experience in similar studies indicates that the

greatest risk in this study to you is the unintentional release of information from your health records. The study doctor will protect your records and keep confidential all the information in your study file, including your name, address and telephone number. The chance that this information will accidentally be given to someone else is small.

You have the right to have any information about you and your health that is collected, used or disclosed for this research study to be handled in a confidential manner.

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your name, address, date of birth, new or existing medical records, that includes types, dates and results of medical tests or procedures.

Access to your personal health information will take place under the supervision of the Principal Investigator. The information that is collected for the study will be kept in a locked and secure area by the study doctor for 5 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the St. Michael's Hospital Ethics Board, a group of people who oversee the ethical conduct of research studies at St. Michael's Hospital

The investigators plan to publish the results of this study. You will not be named in any reports, publications, or presentations that my come from this study. Only group data will be presented.

STUDY RESULTS

As mentioned, the investigators plan to publish the results of this study. Once the study has been completed, you can contact Dr. Samir C. Grover (416-864-5628) to obtain a copy of the results.

POTENTIAL COSTS OF PARTICIPATION AND REIMBURSEMENT TO THE PARTICIPANT

You will not have to pay for any of the procedures involved in this study. There is no reimbursement associated with participation in this study.

COMPENSATION FOR INJURY

If you suffer a physical injury from participation in this study, medical care will be provided to you in the same manner as you would ordinarily obtain any other medical treatment. In no way does signing this form waive your legal rights nor release the study investigators, sponsors, or other involved institutions from their legal and professional responsibilities.

PARTICIPATION AND WITHDRAWAL

Participation in any research study is voluntary. If you choose to participate in this study, you can change your mind without reason and withdraw from the study any time up to 5 years. After 5 years, your data will be anonymized and it will no longer be possible to identify which data are yours. In addition, it you decide to decline participation or withdraw from the study at any time, this will have no impact on the care you or your family will receive at St. Michael's Hospital.

CAN PARTICIPATION IN THIS STUDY END EARLY?

You can choose to end your participation in this study at any time. If you withdraw voluntarily from the study, you are encouraged to contact Dr. Samir C. Grover, Division of Gastroenterology (416-864-5628) immediately.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

The study investigators have the right to stop your participation in the study if it is not in your best interest to continue or if you do not follow study directions.

RESEARCH ETHICS BOARD CONTACT

If you have any questions regarding your rights as a research participant, you may contact Chair of the Research Ethics Board at 416-864-6060 ext. 2557 during business hours.

The study protocol and consent form have been reviewed by a committee called the Research Ethics Board at St. Michael's Hospital. The Research Ethics Board is a group of scientists, medical staff, individuals from other backgrounds (including law and ethics) and members of the community. The committee is established by the hospital to review studies for their scientific and ethical merit. The Board pays special attention to the potential harms and benefits involved in participation to the research participant as well as the benefit to society. The committee is also required to do periodic reviews of ongoing research studies. As part of this review, someone may contact you form the Research Ethics Board to discuss your experience in the research study.

STUDY CONTACTS

If you have any questions, concerns or would like to speak to the study team for any reason, please call Dr. Samir C. Grover at 416-864-5628.

INFORMED CONSENT

Study Title: Gamification of a virtual-reality simulation curriculum in endoscopy: impact on clinical performance

Principal investigator: Dr. Samir C. Grover, MD, MEd, FRCPC
Division of Gastroenterology, Department of Medicine
St. Michael's Hospital, University of Toronto
416-864-5628 (available Mon to Fri 9:00 AM – 5:00 PM)

The research study has been explained to me and my questions have been answered to my satisfaction. I have been informed of the alternatives to participation in this study. I have the right not to participate and the right to withdraw without affecting the quality of medical care at St. Michael's Hospital for me and for other members of my family. As well, the potential harms and benefits (if any) of participating in this research study have been explained to me. I have been told that I have not waived my legal rights nor released the investigators, sponsors, or involved institutions of their legal and professional responsibilities. I know that I may ask now, or in the future, any questions I have about the study. I have been told that study records relating to me will be kept confidential and that no information will be disclosed without my permission unless required by law. I have been given sufficient time to read the above information.

I consent to participate. I have been told that I will be given a signed copy of this consent form.

_____ _____
Signature Date

☐ I **agree** to allow my colonoscopy procedure to be videotaped during this study as described in this consent form.

☐ I **do not agree** to allow my colonoscopy procedure to be videotaped during this study as described in this consent form.

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____ _____ _____
Name of person obtaining consent (print) Signature Date

ASSISTANCE DECLARATION □ (check here if not applicable)

The participant/substitute decision-maker was assisted during the consent process as follows (please check the relevant box and complete the signature space below):

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered..

I have been requested to interpret the consent discussion for the potential research participant (_____). I am competent in the English language and in the language of choice of the potential participant (_____). I am not involved in the research study. I agree to keep confidential all personal information of the potential participant. I have interpreted the consent discussion. The potential participant has advised me in his/her own language that he/she has been informed about the research study, the nature and extent of his/her participation, including the risks involved. The potential participant freely gives his/her consent to participate in this study.

_____	_____	_____	
Printed Name of Interpreter	Signature	of Interpreter	Date

_____	_____
Relationship or Position of Interpreter	Contact Information of Interpreter

☐ The consent form was read to the participant/substitute decision-maker, and the person signing below attests that the study was accurately explained to, and apparently understood by, the participant/substitute decision-maker.

_____	_____	_____ Print
Name of Witness	Signature	Date

_____
Relationship to Participant

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
	2b	All items from the World Health Organization Trial Registration Data Set
Protocol version	3	Date and version identifier
Funding	4	Sources and types of financial, material, and other support
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
	5b	Name and contact information for the trial sponsor
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
	6b	Explanation for choice of comparators
Objectives	7	Specific objectives or hypotheses
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
Ethics and dissemination		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.