

Appendix D: CLEAN Wound Study within a Trial (SWAT)

Title: Interventions to Optimize Response Rates for Online, Patient-Reported Outcome Measures (PROMs) - *A SWAT within the CLEAN Wound Trial*

Background and Rationale

Patient-reported outcome measures (PROMs) are a crucial component of pragmatic, patient-centred randomized controlled trials (RCTs). Given that they provide unique information from the patient perspective, their inclusion helps to ensure that the effect of the trial intervention(s) is evaluated in a comprehensive manner.¹ While electronic capture of PROMs has many advantages relative to traditional, paper-based PROMs; which are resource-intensive and prone to error,² response rates are suboptimal, limiting validity and applicability.³ Better strategies to improve the completion of online PROMs are vital to ensure trial validity and maximize efficiency of trial conduct.

We propose a study within a trial (SWAT) to test specific interventions to maximize the response rates of PROM surveys. Specifically, we will explore the impact of two areas of uncertainty^{4,5}: (1) Using different tones in email reminders to participants; (2) Offering participants monetary or non-monetary incentives to increase completion of surveys.

Providing encouragement and offering incentives are recommended strategies to minimize missing PROM data, although evidence to support the effectiveness of each these is lacking or conflicting.⁵ A Cochrane Review reported that the odds of response to a postal questionnaire were increased by over a half when a monetary incentive rather than a non-monetary incentive was used (13 trials, 26,484 participants; OR 1.62; 95% CI 1.39 to 1.88), though there was significant heterogeneity among the results.³ The review included only two trials that evaluated the effect of a monetary rather than a non-monetary incentive on electronic questionnaire response, with no evidence of an effect (OR 0.77; 95% CI 0.48 to 1.23).³ A more recent Cochrane Review examined the effect of strategies to improve retention of participants in RCTs,

including the use of reminders. The authors concluded that none of the comparisons provided high-quality evidence, emphasizing the need for further studies. The use of electronic reminders was highlighted as a key recommendation for future research.⁶ Particularly relevant to this SWAT, a factorial trial of the effectiveness of pre-notification and use of a pleading (vs. non-pleading) tone in email reminders on survey response found weak evidence that the pleading tone increased response, though the trial was too small to detect the effects of the interventions.⁴

Objective(s)

- 1) To evaluate the effect of using different tones in email reminders to participants on the PROM survey response rate
- 2) To evaluate the effect of offering participants a monetary versus non-monetary incentive on the PROM survey response rate

Study Design

This SWAT will use a two-by-two factorial RCT design (Table 1) to allow the simultaneous comparison of the effects of using different tones in email reminders to participants and offering a monetary or non-monetary incentive on the PROM survey response rate. Upon scheduling of their surgery, eligible CLEAN Wound participants will be enrolled automatically into the SWAT using web-based randomization. Participants will be randomized with equal (1:1:1:1) allocation to the four groups, stratified by site. No additional consent steps will be required (relative to the CLEAN Wound procedures) as participants will not be informed about their inclusion in the SWAT, given the low-risk nature of the study (and to minimize bias).

		<i>Incentive</i>	
<i>Tone of reminder email</i>	Duty-laden	Monetary	Non-monetary
		Duty-laden reminder / monetary incentive	Duty-laden reminder / non-monetary incentive
	Encouragement-laden		
		Encouragement-laden reminder / monetary incentive	Encouragement-laden reminder / non-monetary incentive

Table 1 – 2x2 Factorial Design of the SWAT

Interventions and Comparators

1) Reminder email tone – Participants will be randomized to receive a duty-laden or encouragement-laden reminder (at 2 days, and again at 4 days, as needed) by email if they do not respond to the initial electronic survey invitation. The email reminders were developed in collaboration with our patient partners, and are available in the Supplementary Material of this Appendix.

2) Incentive upon survey completion – Participants will be randomized to receive a small monetary incentive (e.g., \$5 gift card) or non-monetary incentive (e.g., entry into a draw, with 1 in 500 chance of winning a \$2500 gift card) incentive upon completion of their survey, with total value equal between the two arms. Participants will be informed of the monetary or non-monetary incentive in their initial survey invitation and in their reminders.

Eligibility Criteria

The SWAT eligibility criteria will be the same as the CLEAN Wound eligibility criteria, with two additional criteria: provision of an email address (in order to receive the SWAT interventions) and a scheduled date of surgery, in order to minimize potential losses due to early withdrawal.

Outcome Measures

The primary outcome is the completion of the PROM survey, collected 30 days after surgery.

The secondary outcome is participants' perception(s) of the SWAT interventions, assessed using qualitative methods. Participants' perception(s) of the interventions will be collected and analyzed through in-depth, semi-structured qualitative interviews.⁷ Conducted conversationally with one respondent at a time, semi-structured interviews involve a blend of closed- and open-ended questions, accompanied by follow-up 'why' or 'how' probes and are informed by an interview guide developed *a priori* (and which may be iteratively refined depending on the direction of the inquiry). The interview guide is available in the Supplementary Material of this Appendix. They will be conducted virtually or by phone by a PhD-trained researcher with

extensive experience in qualitative methods and supplemented with field notes to collect contextual information, as needed. The interviews will be audio-taped, sent using secure file transfer to a HIPPA compliant external transcription service and transcribed verbatim. Participants who prefer not to be recorded will have their answers recorded using field notes. We anticipate that the interviews will last approximately 30-60 minutes each. All qualitative data will be managed using NVivo qualitative software.⁸

Sample Size

Primary outcome: Our sample size calculation assumes a baseline response rate of 80% (from our pilot CLEAN Wound Trial) and no interaction between the incentive and tone of email reminder interventions. A sample size of 1000 participants provides 80% power to detect an OR=1.6 and 90% power to detect an OR=1.8 for both intervention comparisons, consistent with prior effect estimates.

Qualitative component: We will use a purposeful sampling technique⁹ to ensure maximum variation in key demographics within the sample of SWAT participants. The final sample size for the qualitative study will be determined by thematic saturation (i.e., the point at which the team agrees that most viewpoints are fully accounted for, and successive interviews are not expected to provide new insight).¹⁰ Based on our previous research exploring patients' perceptions, we estimate that interviews with approximately 25-30 participants will be needed to achieve thematic saturation.

Analysis Plan

The primary analyses will compare the completion of the PROMs across the 4 groups. Between-group comparisons will be made for each strategy using multivariable logistic regression models. Interaction between strategies will be investigated by including an interaction term in the regression model. In the absence of any evidence for such an interaction, the main effects for each of the factorial elements will be estimated, along with their 95% confidence intervals.

In keeping with the iterative nature of qualitative methodology, the qualitative analysis will co-occur with data collection to continuously monitor emerging themes. Interviews will be analyzed using a thematic analysis approach, enabling the identification of patterns of experience and meaning.^{11,12} We will extract and collate interview sections that reflect key areas of interest and carry out initial coding, and will then use the emergent codes to guide a de-novo analysis of the entire corpus for overarching sub-themes, using NVivo to record which subthemes occurred in each interview to ensure their accurate representation in the analysis. Subthemes that express similar experiential patterns will be compiled to develop one or two core themes if appropriate.

Registration

This sub-study will be registered on the SWAT repository (<https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>), a publicly available registry that conforms to international standards for registries.

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Supplementary Material: SWAT Email templates and Interview Guide

A) Template: Duty-laden email

Email subject line: CLEAN Wound Trial survey - Please do your part to improve patient care

Dear <<first and last name>>,

The time has come to complete your post-operative survey for the CLEAN Wound Trial. We call on you to support our important research using the following link: <<personalized survey URL>> as soon as you can!

Upon completion of your survey, you will <<insert incentive arm allocation: 1- receive a \$5 Tim Horton's gift card by email; or 2- have a 1 in 500 chance of winning a \$2500 gift card>>.

Please do your part to help others and to advance knowledge. Trial results will be used to improve and standardize practices to prevent surgical site infections. Help us meet our goal of making patient care better in Ontario (and in time, globally)!

If you have any questions:

- *Please refer to the Research Study Information Sheet that you were given when you agreed to participate in the trial for the appropriate contact information; or*
- *An electronic version is available on our website: www.impactsprogram.ca.*

Thank you for your commitment to the IMPACTS Program and the CLEAN Wound trial.

NOTE: This is an automated email - please do not reply to this email.

*Thank you,
The IMPACTS team*

B) Template: Encouragement-laden email

Email subject line: *CLEAN Wound Trial Survey – Please help improve patient recovery*

Dear <<first and last name>>,

Thank you for participating in the IMPACTS Program and the CLEAN Wound Trial!

As a key last step, we encourage you to share your insights about your recovery by answering a survey. You may access it using the following link: <<personalized survey URL>>.

Upon completion of your survey, you will <<insert incentive arm allocation: 1- receive a \$5 Tim Horton's gift card by email; or 2- have a 1 in 500 chance of winning a \$2500 gift card >>.

We really appreciate your input!

If you have any questions:

- *Please refer to the Research Study Information Sheet that you were given when you agreed to participate in the trial for the appropriate contact information; or*
- *An electronic version is available on our website: www.impactsprogram.ca.*

Thank you for your contribution to the IMPACTS Program and the CLEAN Wound trial.

NOTE: This is an automated email - please do not reply to this email.

*Thank you,
The IMPACTS team*

C) Interview Guide

Background: The secondary outcome of this Study within a Trial (SWAT) is participants' perception(s) of specific interventions (tone of email, and monetary or non-monetary incentive) to increase patient-reported outcome measure (PROM) response, assessed using qualitative methods. The following interview guide will be used to gather relevant data for that outcome from patients included in the SWAT. Participants will be recruited from all four randomization groups, and we expect to interview approximately 25-30 participants. The interviews are designed to take approximately 30 minutes.

Pre-amble (spoken by interviewer to participant)

Thank you very much for participating in this study, and for agreeing to be interviewed. The purpose of this interview is to learn about your experience in the CLEAN Wound Trial, and in particular, your thoughts and feedback about the follow-up email communication(s) and survey that you were asked to complete. This will help us to optimize participant response rate(s) to

online surveys in the future. In order to capture all of your feedback, would it be okay with you if I record this conversation? Once it is transcribed and de-identified for analysis, the audio file will also be destroyed.

1. So to begin, can you tell me a little bit about yourself?

- *Global question(s) to open conversation, just a few points about themselves, keep it brief*
- *What led you to want to participate in the CLEAN Wound trial?*

2. If you recall, at 30 days after your surgery, you were sent an invitation (by email) to complete a survey.

- *Did you complete the survey? If not, why not?*
- *What do you remember about the email?*
- *Did it motivate you to complete your survey? Why/why not?*
- *How did you find the wording of the email? Overall impressions? What did you find most compelling?*

3. A reminder email was automatically sent 2 and 4 days later (as needed).

- *Did you need a reminder or did you complete it upon receiving the initial invitation?*
- *If you received reminder(s), tell me a bit about how you found receiving the reminders?*

4. How did you find the survey?

- *Are you normally someone who fills out surveys when asked?*
- *Do you prefer to complete surveys independently or with assistance?*
- *What motivated you to complete the survey? If not applicable, can ask in general, what motivates you to complete surveys?*
- *Was there anything that discouraged you from completing the survey?*

5. Did you receive a gift card or entry into a lottery as part of the study (i.e., upon survey completion)? What were your thoughts on that?

- *If GC, probe whether it helped or would have done it without money*
- *If entry into a lottery, probe thoughts on that as an incentive*
- *If incentive deemed helpful, which type (i.e., guaranteed small GC or a chance to win a larger prize in a lottery) is better and why?*

6. Is there any other feedback about how to encourage completion of online surveys (or anything else) that you would like to share?

- *Any feedback about your experience as a participant in this trial?*

Post-amble Interviewer: Thank you very much for your time and for sharing your thoughts with me. We will be combining the information we hear from everyone and analyzing it later this month. Once we have the results, we will share a summary with all of the participants via email.

End of Interview.