SWAT 126: Feasibility and diagnostic accuracy of Telephone Administration of an adapted patient-reported Wound HeaLth QuestiONnaire for assessing surgical site infection following abdominal surgery in low- and middle-income countries (TALON)

Objective of this SWAT
TALON is a multi-centre, international, non-randomised Study Within a Trial, divided into two sections (TALON-1 and TALON-2). The overall aim is to evaluate the feasibility and validity of telephone administration of a patient-reported questionnaire for wound follow-up in low resource settings. The objectives and methods for TALON-1 and TALON-2 will be presented separately.

TALON-1: Objectives
(1) To assess patient acceptability, cross-cultural and cross-language equivalence, and content validity of the Wound Healing Questionnaire (WHQ) across different low- and middle-income countries (LMICs).
(2) To assess the scaling and psychometric properties of the WHQ when used across different patient populations and subgroups.
(3) To adapt the WHQ to improve validity of this patient reported outcome measure (PROM) across different LMICs.

TALON-2: Objectives
(1) To evaluate the diagnostic accuracy of telephone administration of the WHQ for assessing abdominal surgical site infection across LMICs.
(2) To assess the feasibility of delivery of the telephone WHQ by a non-surgeon researcher within the FALCON, ChEETAh and PENGUIN trials.
(3) To assess the feasibility of wound photography as a diagnostic adjunct for telephone-based wound follow-up.

Study area: Follow-up, Retention
Sample type: Participants
Estimated funding level needed: Medium

Background
The current ‘gold standard’ for assessment of surgical site infection (SSI) during the 30 days after surgery is in-person review according to US Centre for Disease Control (CDC) criteria (1). However, in-person assessment is labour and time intensive, and requires patients to take additional time-off work and incur costs of travel. More efficient follow-up pathways are required, for example over the telephone, which are of comparable quality to in-person wound assessment.

TALON will be run first within FALCON, a pragmatic multicentre factorial randomised trial testing measures to reduce SSI in LMICs, but will also be adopted into future trials (ChEETAh: A cluster randomised trial of an in-theatre intervention to reduce SSI, and PENGUIN: A 2x2 factorial trial in the perioperative setting to reduce the risk of SSI and pulmonary complications after midline laparotomy). Telephone follow-up became essential during the COVID-19 pandemic for ongoing follow-up of already recruited and newly recruited FALCON patients, and became routine practice within FALCON trial pathways from 1 April 2020.

Interventions and comparators
Intervention 1: Telephone-based administration of a patient-reported Wound Healing Questionnaire. The questionnaire will be delivered integrated into the FALCON trial pathway for included patients. The telephone-based WHQ will be performed at 28-30 days (i.e. in the 72 hours before in-person follow-up) by a non-surgeon researcher, according to a telephone script. Patients will be asked to provide between 1 and 3 telephone contact numbers, either personal or belonging to a family member or community worker. The non-surgeon researcher directing completion of the WHQ should be blinded to the outcome of wound assessment within the FALCON trial. In the event that the patient is unable to be contacted by telephone at 27-30 postoperative days (before in-person follow-up), the WHQ should be performed at the in-person follow-up appointment, where possible, by a non-surgeon researcher who is independent of the clinician’s assessment for the FALCON primary outcome, to ensure independent measures are taken.

Intervention 2: ‘Gold standard’ in-person wound assessment at 30-days after surgery (with Day 0 as the day of surgery) by a trained clinician according to CDC criteria for diagnosis of surgical site infection.

Index Type: Method of Follow-up

Method for allocating to intervention or comparator
Within patient comparison (patient will receive both assessments)

Outcome measures
Primary: Proportion of SSI that are correctly identified by the telephone WHQ, summarised using measures of diagnostic test accuracy
Secondary: Telephone contact rate (proportion of patients successfully contacted by telephone); return rate (proportion of telephone WHQ returned, and reasons not completed); data completion rate (proportion of missing data within each form); attrition benefit (ratio of the proportion of recruited patients returning a telephone WHQ to the proportion of recruited patients completing in-person follow-up)

Analysis plans
TALON-2 will be reported according to Standards for Reporting of Diagnostic Accuracy Studies (STARD) (2). Statistical analysis will be undertaken using R Project for Statistical Computing (V3.6.1). The outcome against which the WHQ prediction model will be validated is 30-day in-person wound assessment according to the CDC criteria (binary outcome: SSI / no SSI). Blinded 30-day outcome data for patients included in TALON will be made available by the FALCON Trial Management Group for this analysis. Psychometric properties of the questionnaire will be analysed using Rasch Unidimensional Measurement Modelling, exploring Differential Item Functioning across different countries, languages and cultural groups. A full statistical analysis plan is available at www.globalsurg.org.

Possible problems in implementing this SWAT
Ethical amendments to study protocol across 5 to 10 LMICs.
Training of site investigators to deliver the questionnaire in a standardised fashion.
Ensuring high case ascertainment and delivery of the questionnaire before in-person follow-up.
Ensuring data are recorded for non-contactable patients to avoid underestimation of loss to follow-up.

References
1. Horan TC, Andrus M, Dudeck MA. CDC/NHSN surveillance definition of health care-associated infection and criteria for specific types of infections in the acute care setting. Am J Infect Control. 2008;36(5):309-32.
2. Cohen JF, Korevaar DA, Altman DG, Bruns DE, Gatsonis CA, Hooft L, et al. STARD 2015 guidelines for reporting diagnostic accuracy studies: explanation and elaboration. BMJ Open. 2016;6(11):e012799.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

People to show as the source of this idea: James Glasbey, Aneel Bhangu; NIHR Global Health Research Unit on Global Surgery
Contact email address: j.glasbey@bham.ac.uk
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Revisions made by:
Date of revisions: