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ASSIST: Development of a Simplified Clinician–Patient Hybrid Reporting Outcome Measure for Remote Diagnosis of Surgical Site Infection

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ABSTRACT

Remote assessment of surgical site infection(SSI) lacks sensitivity for the diagnosis of SSI, but current evidence has not evaluated whether a combination of photographs and questionnaires improves diagnostic accuracy. This study aims to develop a remote diagnostic measure to identify SSI. A two-phase mixed methods study was conducted. In phase I, five clinicians reviewed the Bluebelle wound healing questionnaire(WHQ) on a five-point Likert scale of agreement for inclusion in a remote measure. Discussion generated a hypothesis as to which items should be included. In phase II, a cohort study, whereby clinicians evaluated patient's wound images and patients completed the WHQ, were reviewed for scale structure. Principal component analysis (PCA) with scree plot examination and maximum likelihood of estimation (MLE) for one, two and three factors were evaluated. Internal consistency was assessed with Cronbach's α. Phase I: hypothesis generation estimated a measure containing between 10 and 12 items would include all relevant items without ambiguity or redundancy. Phase II: a combined sample of 570 responses provided clinician reviewed images and patient responses. PCA suggested that a 12-item measure with a combined variance of 60.2% would have the best model fit. Cronbach's α was high at 0.841. One included item was highlighted as potentially ambiguous in phase I (wound pain), providing an additional model with this removed. MLE for one, two and three factors suggested measures with 8, 10 and 11 items, respectively. Total variances were low at 29.7%, 39.8% and 41.4% and Cronbach's α were high at 0.838, 0.827 and 0.823, respectively. Three potential models for a remote diagnostic measure were identified. Each is shorter than alternative available measures, which have not been designed for combined use, ensuring this is easy to use. Further evaluation for reliability and diagnostic accuracy is needed to validate a final measure that can be implemented in clinical practice.

1 | Background

Surgical site infections (SSIs) are a frequent and problematic complication for all surgical specialties. In vascular surgery, the incidence of SSI can be as high as 40% in lower limb arterial procedures [1]. Infections result in additional healthcare appointments, prolonged wound healing and psychological distress [2, 3]. Most SSI can be managed with oral antibiotics in the community, though severe infections can necessitate further hospitalisation, surgical intervention and limb loss or mortality in some cases [4, 5]. The impact of a single SSI goes further, with estimated financial costs in the region of £3776–£6103 and

Summary

- This paper outlines the development of a novel remote diagnostic measure to identify surgical site infection.
- Using a methodological process, five potential measures are developed.
- The measures will be evaluated for acceptability, reliability and diagnostic accuracy in a further study, identifying the best measure to be used in practice.
- This study is the first step towards answering knowledge gaps identified in a previous meta-analysis where a combination of wound images and patient-reported questionnaires have not been evaluated in this manner previously.

environmental costs 60-fold higher than those without infection at 643.8 $kgCO_2e$ per SSI [6, 7].

Over 3 million procedures were performed in the reduced capacity NHS during 2020, with a median of 4 685 106 procedures per year prior to this [8]. To review each patient face-to-face postoperatively would require every surgical consultant in the NHS to see 15 patients every week, in addition to new referrals and routine follow-ups. Given that most patients have an uncomplicated postoperative trajectory, this limited capacity for review, remote assessment offers the prospect of effective triage and streaming of patients through postoperative pathways, either face-to-face or an alternative.

Using telemedicine by either synchronous or asynchronous methods improves patient experience and reduces impact on the environment, in line with national net zero targets [9–11]. Current evidence suggests that remote assessment has been deployed using telephone-, photograph- or questionnaire-based methods in isolation. This implementation allows for screening patients but lacks sensitivity to diagnose SSI remotely [12]. A combination of modalities, such as wound photographs with patient questionnaire responses, have not been developed and evaluated together to assess diagnostic accuracy. Further, remote assessment has not been evidenced in elderly populations, who may derive more benefit from its use but are more likely to be digitally naïve and struggle with utilisation.

The Bluebelle wound healing questionnaire (WHQ) is a 19-item patient- or clinician-reported questionnaire, which was developed and validated in general (abdominal) surgery [13, 14]. This was based upon the existing gold standard for diagnosis, which is a face-to-face assessment using the Centres for Disease Control and Prevention (CDC) criteria [15]. Alternative measures include the ASEPSIS criteria and the Southampton score [16, 17]. The WHQ has visual elements relating to a patient's wound and items on other signs, symptoms and interventions for infections and therefore could potentially form the basis of a mixed modality remote diagnostic measure.

The necessity for improved service configuration and consistent assessment and diagnosis of patients with wounds has been recognised by both patients and clinicians in James Lind Alliance Priority Setting Partnerships [18]. This study aimed to develop a novel remote SSI assessment measure by combining photograph and questionnaire modalities.

2 | Methods

2.1 | Study Design

This mixed methods study consists of outcome measure development in three phases:

- Phase I—clinician review of the existing WHQ measure [14] and creation of an outcome measure hypothesis.
- Phase II—a prospective observational cohort to explore which items should be included in the final measure, testing the initial hypotheses.
- Phase III will then be the validation of the ASSIST measure and will be described elsewhere.

The COSMIN study design checklist for patient-reported outcome measures was used to guide study design, sample size calculation and hypothesis formulation and testing [19]. All participants provided written consent as part of an ongoing randomised controlled trial (NCT02992951). Ethical approval for this trial was obtained (16/LO/2135) from the London—Harrow Research Ethics Committee, and study conduct was in accordance with the Declaration of Helsinki (2013) [20]. Eligibility criteria followed the parent trial including all capacitous adult patients undergoing clean or clean-contaminated lower limb vascular surgery. Patients on concurrent antibiotics at the time of screening for conditions not related to the index procedure were not eligible for enrolment. Participants were recruited between 8th June 2022 and 9th January 2024 in a tertiary vascular centre in the United Kingdom (UK).

2.2 | Phase I: Hypothesis Generation

The Bluebelle WHQ is a validated 19-item patient- or clinician-observed questionnaire for the identification of SSI in primarily closed wounds in general surgery. It includes 11 WHQ items related to signs and symptoms of possible SSI (six visual; erythema, serous exudate, haemoserous exudate, purulent exudate, superficial dehiscence and deep dehiscence and five non-visual; wound warmth, swelling, smell and pain, and systemic temperature), with response categories for: 'not at all' (score 0), 'a little' (1), 'quite a bit' (2) and 'a lot' (3). A further eight items relate to wound care interventions (sought wound care advice, application of a dressing, return to hospital, use of antibiotics for the wound, deliberate wound separation by healthcare professional, wound debridement, wound drainage, operation under general anaesthetic, GA). Response categories for interventions are yes (score 1) and no (score 0).

Five authors (RL, LH, BR, JW, MS), four vascular and one general surgeon, individually reviewed all 19 items of the WHQ, scoring each on a five-point Likert scale (1—strongly disagree, 2—disagree, 3—neither agree or disagree, 4—agree and 5—strongly agree) of agreement for necessity to diagnose SSI when considering the possibility of ambiguous interpretation of the item. Views were explored around the necessity of items to identify SSI and where these could be misinterpreted by patients and hence scored in the absence of SSI. The mean Likert ratings for each item were taken, with 1.0–2.4 indicating disagreement, 2.5–3.4 uncertainty and 3.5–5.0 agreement that items should be included. These scores were combined with the qualitative discussion to formulate a priori hypotheses around which items should be retained within the ASSIST measure.

2.3 | Phase II: Cohort Study

Participants enrolled into the cohort study were followed up at 30 days post-operatively or before if they presented prior to this with a wound problem; their review was conducted at that time. All participants received both a remote and face-to-face assessment. Each were asked to complete all 19 items of the WHQ remotely and additionally submit a wound photograph to their clinical team. Where this was not possible, relatives, carers and community nurses provided these images or, as a last resort, this was taken in person. At a face-to-face review, which occurred on the same day as remote submission, a clinician blinded to the remote assessment made a reference diagnosis as per the Centres for Disease Control and Prevention (CDC) criteria for SSI.

2.4 | Sample Size

The COSMIN Study Design checklist guided appropriate sample size estimations for structural validity factor analysis (five to seven times the number of construct items and ≥100 participants) and internal consistency (≥100 participants). Accounting for a 20% attrition rate, a sample size of 140 participants would provide 115 responses ensuring appropriate outcomes. Additionally, combining the reviews of five reviewers would therefore provide an inflated sample of 575 participants.

2.5 | Data Analyses

Exploratory factor analyses examined the structure and constructs of the measure. Analyses were conducted from a combined clinician photograph review (of the six visual items) and patient responses to the remaining 13 items using a combined dataset from all five reviewers.

For each analysis, all iterations of item pairs were explored using Pearson's correlation coefficients. Correlation matrix determinants <0.00001 were explored for cases of multicollinearity. Pairs with high correlations ($r > 0.8$) were appraised for similarity and redundancy considered with exclusion before conducting factor analyses [21].

Four factor analysis models were run, principal component analysis (PCA) with scree plot examination for the determination of factor extraction based upon eigenvalues greater than one and maximum likelihood of estimation specifying one, two, and three factors. The Kaiser–Meyer–Olkin (KMO) measure of sample adequacy was accepted with values >0.5, with values approaching 1.0 considered excellent. Significant values (<0.05) for Bartlett's test of sphericity ensured that correlation matrices were not identity matrices. Oblique (promax with Kaiser normalisation, $\kappa = 4$) rotations were explored for model fit. Small coefficient loadings below 0.5 were suppressed, and items with no or cross-loading were considered for exclusion. Residuals were evaluated to ensure the adequacy of each factor analysis. Where $<50\%$ of nonredundant residuals had absolute values >0.05 indicated good model fit.

Internal consistency of the scales identified from factor analyses were evaluated with Cronbach's α coefficient. Values >0.7 were considered to have good internal consistency.

All data were collected and analysed using IBM SPSS (IBM SPSS Corporation, version 28; Rochester, New York).

3 | Results

3.1 | Phase I: Hypothesis Generation

All five reviewers evaluated each WHQ item in the context of clinician and patient responses. For clinician responses, there was no mean disagreement for any item (all items had means >3.4), and two items indicated strong agreement for inclusion, erythema (mean 4.6) and purulent exudate (mean 4.8). Comments indicated reasons for ambivalence over other items; serous exudate could be 'part of the healing process', haemoserous exudate may indicate a 'herald bleed' and dehiscence may be caused by SSI but also other patient factors such as 'nutrition, diabetes and operative technique'. It was also felt that it can be 'challenging to evaluate the depth' of exudate and deep dehiscence over photos. After discussion, the reviewers felt on balance, the measure should include all these items when wounds are reviewed by a clinician.

For patient-reported items, most found that wound swelling (mean 2.2) and use of a wound dressing (mean 1.4) would not be a necessity in this context (Table 1). This was corroborated with a discussion 'swelling could be from other causes e.g. oedema' and 'dressings often used post-operatively', indicating that reviewers felt these items would be potential sources for ambiguity or redundancy in the measure. There was some agreement for the inclusion of wound pain (mean 3.6), systemic fever (mean 3.6), wound deliberately opened (mean 3.6) and sought advice for wound problem (mean 3.4). Opinions for these items included pain being 'subjective', and some patients may perceive 'expected postoperative pain as abnormal'; systemic fever could be due to 'other sources, e.g., respiratory', wound deliberately opened may be mistaken during 'normal practices such as removal of staples or non-absorbable suture', and sought wound advice, the patient may have had 'non-infection related issues' with the wound. Additional opinions felt that operation under GA could have been for problems other than infection. In the discussion, there seemed to be four items with similar operative management themes: wound deliberately opened, wound debridement, wound drainage and operation under general anaesthetic (items 16–19), which may skew results and while they are indicators of SSI, they may not be relevant to a remote diagnostic measure. It was concluded that potentially only one of the operative items should be included, which would likely be items 17 or 18

TABLE 1 | Likert responses of agreement for necessity to diagnose SSI in a combined clinician–patient remote outcome measure. Score legend; strongly disagree (1), disagree (2), neither agree nor disagree (3), agree (4), strongly agree (5). The mean reviewer score presented on the far right column.

		Reviewer					
		1	2	3	4	5	Mean
Questions to be answered by clinicians							
1.	Was there redness spreading away from the wound? (erythema/cellulitis)	5	5	4	5	4	4.6
2.	Has any part of the wound leaked clear fluid? (serous exudate)	5	4	2	4	2	3.4
3.	Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	5	2	4	4	2	3.4
4.	Has any part of the wound leaked thick and yellow/green fluid? (pus/purulent exudate)	5	5	5	5	4	4.8
5.	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	5	4	2	2	4	3.4
6.	Did the deeper tissue also separate?	5	4	4	2	4	3.8
Questions to be answered by patients							
7.	Was the area around the wound warmer than the surrounding skin?	5	5	5	4	4	4.6
8.	Has the area around the wound become swollen?	1	2	4	2	2	2.2
9.	Has the wound been smelly?	5	5	5	4	2	4.2
10.	Has the wound been painful to touch?	2	4	4	4	4	3.6
11.	Have you had, or felt like you have had, a raised temperature or fever? (fever > 38°C)	1	5	4	4	4	3.6
12.	Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	4	5	2	4	2	3.4
13.	Has anything been put on the skin to cover the wound? (dressing)	1	2	2	1	1	1.4
14.	Have you been back into hospital for treatment of a problem with your wound?	4	5	4	4	2	3.8
15.	Have you been given antibiotics for a problem with your wound?	5	5	4	5	4	4.6
16.	Have the edges of your wound been deliberately separated by a doctor or nurse?	2	5	4	3	4	3.6
17.	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	2	5	5	5	4	4.2
18.	Has your wound been drained? (drainage of pus/abscess)	2	5	5	5	4	4.2
19.	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	2	5	5	4	4	4.0

(wound debridement, wound drainage). Additionally, reviewers determined that wound swelling, pain, systemic fever, use of dressing and potentially sought wound advice would be sources of ambiguity and therefore should be removed.

The final hypothesis was that the final measure would include between 10 and 12 items, which would comprise all six visual elements (items 1–6), wound warmth (item 7), wound smell (item 9), return to hospital (item 14), use of antibiotics (item 15) and with or without, seeking wound advice (item 12) and either of wound debridement (item 17) or wound drainage (item 18).

3.2 | Phase II: Cohort Study

In total, 140 participants were included over the study period (Figure 1). There were six (4.3%) participants followed up who completed the questionnaire but did not provide a wound image and therefore were excluded from the final analysis. These six participants were of similar age (65.3 ± 14.3 years), had lower body mass index (BMI, 22.5 ± 2.3) and fewer comorbidities (2.8 ± 1.9) than the whole cohort (Table 2). None were complicated with SSI. Reasons for no image provided included having no email address and unable to use a smartphone. This left 114 (81.4% of all participants and 87.7% of participants able to provide review) participants who provided both wound images and WHQ at follow-up. A final combined sample comprising all five reviewers therefore contained 570 responses. SSI was present in 29 of the 114 participants (SSI rate; 25.4%).

3.2.1 | Principal Component Analysis

A high correlation was not observed between any of the 19 Bluebelle WHQ item pairs, and the matrix determinant

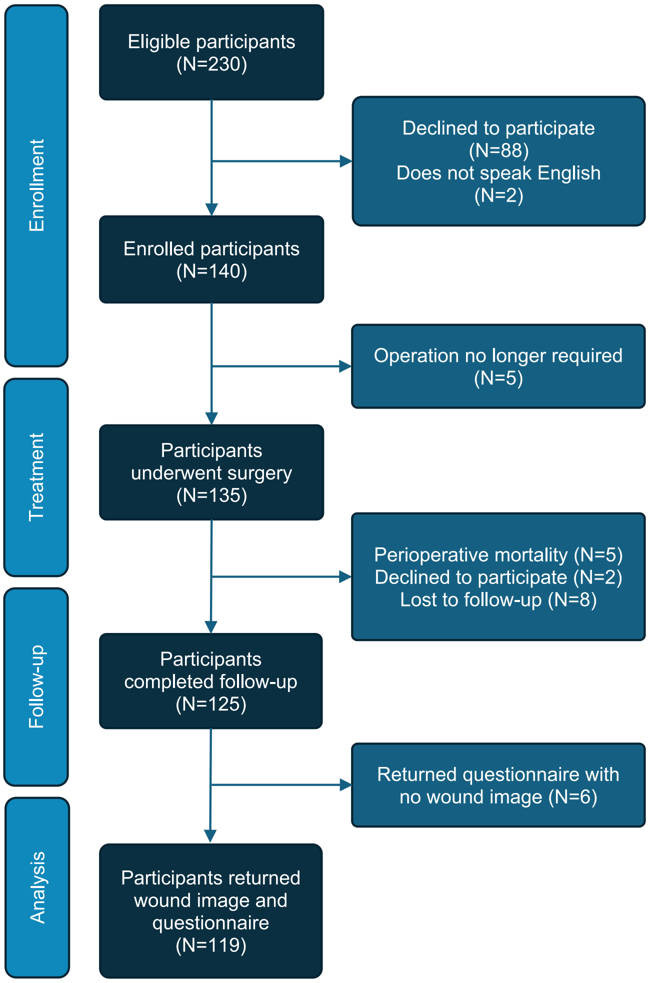

FIGURE 1 | Study participant flow chart.

TABLE 2 | Baseline characteristics of participants.

Characteristic	*N* (140)	(%)
Sex		
Female	39	27.9
Male	101	72.1
Age[a]	65.5	12.7
BMI[a]	26.2	6.4
Ethnicity		
Caucasian	140	100
Smoking history		
Current	50	35.7
Ex-smoker	71	50.7
Never smoked	19	13.6
Comorbidities		
Diabetes	58	41.4
Previous cerebrovascular accident	13	9.3
Hypertension	77	55.0
Cardiovascular disease	55	39.3
Peripheral vascular disease	124	88.6
Chronic obstructive pulmonary disease	41	29.3
Chronic kidney disease	25	17.9
Dermatological disease	14	10.0
Gastrointestinal disease	43	30.7
Musculoskeletal disease	38	27.1
Previous operation	88	62.9
Mean number of comorbidities per patient[a]	4.1	2.0

Abbreviation: BMI, body mass index.
[a]Values presented as mean and standard deviation.

was 0.001, indicating the absence of any multicollinearity (Table 3). The sample was middling (KMO = 0.793), and there was no indication of an identity matrix ($X^2 = 4146.5$, $p < 0.001$). In the initial extraction, PCA found five factors with eigenvalues greater than one and a combined variance of 61.4%. There was, however, no loading above the threshold on two of these factors, and scree plot analysis suggested that three factors would provide a better model fit (Figure 2). Low communalities (< 0.300) were found for items 8 (wound swelling, 0.298), 11 (systemic fever, 0.204) and 13 (wound dressing, 0.028) and therefore were dropped (Table 4). Further, significant cross-loading was identified for the operative items 16 (wound opened), 18 (wound drained) and 19 (operation under GA) (Table 5). In the context of a remote diagnostic measure, the hypothesis generation and significant negative cross-loadings, these items were decidedly removed. Subsequently, item 17 (wound debridement) no longer had a good fit with the model (communality of 0.285) and was also removed. Finally, 12 items were extracted across three factors with a meritorious KMO of 0.824 and no indication of an identity matrix ($X^2 = 2436.1$, $p < 0.001$). The scree plot is shown in Figure 3. There were 31 (46.0%) nonredundant residuals greater than 0.05 between observed and reproduced correlations. The combined variance of the factors accounted for 60.2% of the variance.

Items 1–6 (erythema, serous exudate, haemoserous exudate, purulent exudate, superficial dehiscence and deep dehiscence) all loaded onto factor one (Table 6). Items 12 (sought wound advice), 14 (return to hospital) and 15 (antibiotics) loaded onto factor two and items 7 (wound warmth), 9 (wound smell) and 10 (wound pain) loaded onto factor three. After a discussion, the study team felt the factors appropriately described 'the appearance of the wound' (factor one), 'the treatment(s) given to the patient' (factor two) and 'the feel and smell of the wound' (factor three). There was a debate over factor three describing non-visual signs and symptoms, but the team concluded 'feel and smell' better reflected and distinguished the factors. A more appropriate language for a tool was designed to be used by patients. The total percentage of variance for factors one, two and three was 37.3%, 13.9% and 9.0%, respectively (cumulative total; 60.2%). Cronbach's α was high with a coefficient of 0.841.

TABLE 3 | Correlation matrix for matching Bluebelle wound healing questionnaire response items. The matrix determinant 0.001 does not indicate any multicollinearity.

	Correlation matrix[a]	1. Erythema	2. Serous exudate	3. Haemoserous exudate	4. Purulent exudate	5. Superficial dehiscence	6. Deep dehiscence	7. Wound warmth	8. Wound swelling	9. Wound smell	10. Wound pain	11. Systemic fever	12. Sought wound advice	13. Wound dressing	14. Return to hospital	15. Antibiotics	16. Wound opened	17. Wound debridement	18. Wound drained	19. Operation under GA
1.	Erythema	1.00	0.43	0.30	0.44	0.59	0.42	0.18	0.11	0.25	0.25	0.12	0.38	0.10	0.33	0.40	0.18	0.24	0.19	0.25
2.	Serous exudate	0.43	1.00	0.45	0.38	0.56	0.40	0.11	0.04	0.34	0.19	0.04	0.32	0.07	0.39	0.23	0.36	0.11	0.24	0.14
3.	Haemoserous exudate	0.30	0.45	1.00	0.28	0.42	0.41	0.08	−0.03	0.11	0.11	0.08	0.21	−0.01	0.21	0.10	0.25	0.13	0.33	0.22
4.	Purulent exudate	0.44	0.38	0.28	1.00	0.59	0.63	0.07	0.02	0.24	0.25	0.12	0.23	0.06	0.30	0.21	0.25	0.28	0.26	0.22
5.	Superficial dehiscence	0.59	0.56	0.42	0.59	1.00	0.59	0.13	0.05	0.34	0.30	0.12	0.39	0.10	0.36	0.28	0.26	0.30	0.24	0.21
6.	Deep dehiscence	0.42	0.40	0.41	0.63	0.59	1.00	0.04	−0.01	0.26	0.17	0.07	0.23	0.06	0.31	0.20	0.34	0.32	0.40	0.27
7.	Wound warmth	0.18	0.11	0.08	0.07	0.13	0.04	1.00	0.23	0.40	0.38	0.26	0.44	0.02	0.19	0.39	−0.08	0.32	−0.06	−0.08
8.	Wound swelling	0.11	0.04	−0.03	0.02	0.05	−0.01	0.23	1.00	0.10	0.31	0.21	0.24	0.05	−0.03	0.14	−0.02	0.19	−0.07	−0.02
9.	Wound smell	0.25	0.34	0.11	0.24	0.34	0.26	0.40	0.10	1.00	0.44	0.17	0.33	0.11	0.23	0.04	0.07	0.23	−0.03	−0.04
10.	Wound pain	0.25	0.19	0.11	0.25	0.30	0.17	0.38	0.31	0.44	1.00	0.13	0.33	0.05	0.16	0.14	−0.03	0.25	−0.08	0.05
11.	Systemic fever	0.12	0.04	0.08	0.12	0.12	0.07	0.26	0.21	0.17	0.13	1.00	0.09	−0.08	0.04	0.23	−0.05	0.22	−0.03	−0.05
12.	Sought wound advice	0.38	0.32	0.21	0.23	0.39	0.23	0.44	0.24	0.33	0.33	0.09	1.00	0.22	0.48	0.54	0.21	0.24	0.14	0.21
13.	Wound dressing	0.10	0.07	−0.01	0.06	0.10	0.06	0.02	0.05	0.11	0.05	−0.08	0.22	1.00	0.11	0.05	0.05	0.07	0.03	0.05
14.	Return to hospital	0.33	0.39	0.21	0.30	0.36	0.31	0.19	−0.03	0.23	0.16	0.04	0.48	0.11	1.00	0.34	0.43	0.24	0.30	0.20
15.	Antibiotics	0.40	0.23	0.10	0.21	0.28	0.20	0.39	0.14	0.04	0.14	0.23	0.54	0.05	0.34	1.00	0.24	0.28	0.17	0.24
16.	Wound opened	0.18	0.36	0.25	0.25	0.26	0.34	−0.08	−0.02	0.07	−0.03	−0.05	0.21	0.05	0.43	0.24	1.00	0.30	0.70	0.49
17.	Wound debridement	0.24	0.11	0.13	0.28	0.30	0.32	0.32	0.19	0.23	0.25	0.22	0.24	0.07	0.24	0.28	0.30	1.00	0.44	0.30
18.	Wound drained	0.19	0.24	0.33	0.26	0.24	0.40	−0.06	−0.07	−0.03	−0.08	−0.03	0.14	0.03	0.30	0.17	0.70	0.44	1.00	0.70
19.	Operation under GA	0.25	0.14	0.22	0.22	0.21	0.27	−0.08	−0.02	−0.04	0.05	−0.05	0.21	0.05	0.20	0.24	0.49	0.30	0.70	1.00

[a]Determinant = 0.001.

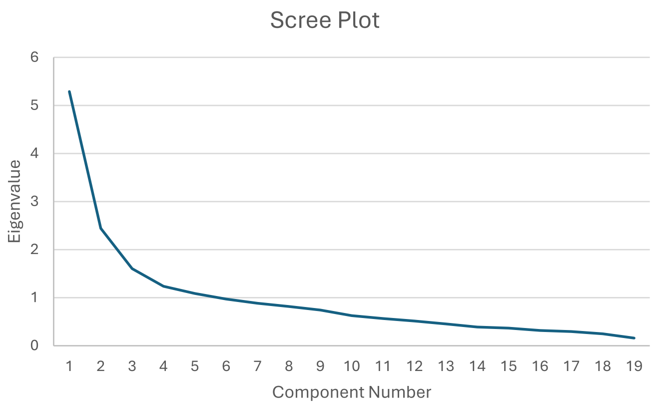

FIGURE 2 | Scree plot for all 19 items extracted by principal component analysis.

TABLE 4 | Table of communalities.

		Communalities	
No.	**Item**	**Initial**	**Extraction**
1.	Erythema	1.000	0.492
2.	Serous exudate	1.000	0.549
3.	Haemoserous exudate	1.000	0.383
4.	Purulent exudate	1.000	0.540
5.	Superficial dehiscence	1.000	0.722
6.	Deep dehiscence	1.000	0.610
7.	Wound warmth	1.000	0.611
8.	Wound swelling	1.000	0.298
9.	Wound smell	1.000	0.447
10.	Wound pain	1.000	0.448
11.	Systemic fever	1.000	0.204
12.	Sought wound advice	1.000	0.555
13.	Wound dressing	1.000	0.028
14.	Return to hospital	1.000	0.378
15.	Antibiotics	1.000	0.486
16.	Wound opened	1.000	0.659
17.	Wound debridement	1.000	0.451
18.	Wound drained	1.000	0.827
19.	Operation under GA	1.000	0.634

Note: Extraction method: principal component analysis.

3.2.2 | Maximum Likelihood of Estimation

The maximum likelihood of estimation models for one, two and three extracted factors specified measures with 8 (Table 7), 10 (Table 8) and 11 (Table 9) items, respectively, though a three-factor model most closely resembled PCA extraction methods. One and two factor solutions were meritorious (KMO = 0.814 and 0.807, respectively), and a three-factor model was middling (KMO = 0.793). No identity matrices were found ($X^2 = 3523.8$, 3872.6 and 4146.5, $p < 0.001$ for factors one, two and three, respectively). Model fit for one-, two- and three-factor models were good with 6 (40.0%), 4 (14.0%) and 51 (29.0%) nonredundant residuals > 0.05, respectively. The total variance explained for one-, two- and three-factors' models were 29.7%, 39.8% and 41.4%, respectively. No cross-loadings were present across two- and three-factor models. Cronbach's α was good with coefficients of 0.838, 0.827 and 0.823, respectively.

TABLE 5 | Component matrix extracted by principal component analysis.

Component matrix[a]			
	Component		
	1	**2**	**3**
Superficial dehiscence	0.763		
Deep dehiscence	0.697		
Erythema	0.667		
Purulent exudate	0.653		
Serous exudate	0.650		
Return to hospital	0.613		
Sought wound advice	0.610		
Wound opened	0.563	−0.554	
Wound debridement	0.527		
Haemoserous exudate	0.521		
Antibiotics	0.516		0.486
Wound drained	0.556	−0.681	
Wound warmth		0.619	0.433
Operation under GA	0.480	−0.558	
Wound pain		0.543	
Wound smell	0.432	0.517	

Note: Extraction method: principal component analysis.
[a]Three components extracted.

4 | Discussion

PCA and maximum likelihood of estimation identified two potential three-factor models for a remote measure to diagnose SSI with 11 and 12 items in each. Hypothesis generation suggested that a measure between 10 and 12 items would comprise all the relevant clinical questions. Overall, the 12-item model appears to have the best fit with the greatest overall variance explained through contained items, though one item, wound pain, was identified as a potential source of ambiguity during hypothesis generation. A third model therefore should be explored with wound pain removed. One- and two-factor solutions explained low levels of variance and did not coincide with the scree plot analysis and so will not be explored further. The next phase in the development of the ASSIST measure will be to validate a remote diagnostic model to identify SSI based upon wound images and questionnaire responses provided by patients. All three of

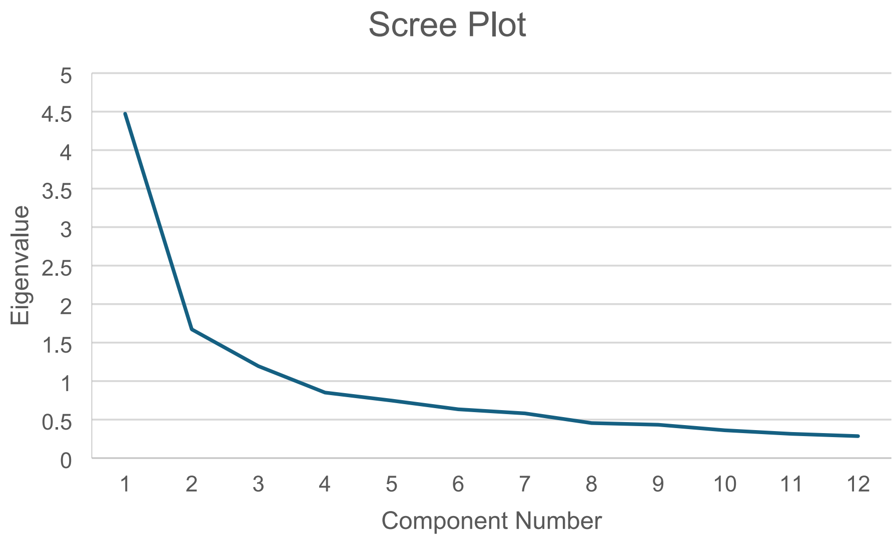

FIGURE 3 | Scree plot for all 12 items extracted by principal component analysis.

TABLE 6 | Pattern matrix of a 12-item model extracted by principal component analysis.

Pattern matrix[a]			
	Component		
	1	2	3
Superficial dehiscence	0.827		
Deep dehiscence	0.781		
Purulent exudate	0.76		
Serous exudate	0.662		
Haemoserous exudate	0.651		
Erythema	0.547		
Antibiotics		0.945	
Sought wound advice		0.735	
Return to hospital		0.549	
Wound smell			0.853
Wound pain			0.809
Wound warmth			0.590

Note: Extraction method: principal component analysis. Rotation method: Promax with Kaiser normalisation.
[a]Rotation converged in five iterations.

TABLE 7 | Factor matrix extracted by maximum likelihood of estimation with one factor.

Factor matrix[a]	
	Factor
	1
Superficial dehiscence	0.786
Deep dehiscence	0.704
Purulent exudate	0.663
Erythema	0.651
Serous exudate	0.636
Return to hospital	0.541
Sought wound advice	0.514
Haemoserous exudate	0.500

Note: Extraction method: maximum likelihood.
[a]One factors extracted. Five iterations required.

the potential models identified here will be evaluated for diagnostic accuracy, in addition to all 19 items of the Bluebelle WHQ with the best taken into the ASSIST measure.

Current evidence suggests that remote assessments have been used by either telephone-, photograph- or questionnaire-based methods in isolation and are able to screen for but not diagnose SSI [12]. The ASSIST measure combines both photograph and questionnaire assessment in a single measure. Further validation will show whether this improves diagnostic accuracy to identify postoperative infections. Accurate remote assessment will ensure efficient triage of complications, enabling 'remote first' approaches to postoperative care and safeguarding patients from unnecessary return visits to hospital. This transition to 'remote first' postoperative care is also a key factor in reducing increasing carbon emissions from patient travel, which have almost doubled in the last three decades [10, 22]. Postdischarge surveillance with serial assessments has been utilised with high response rates and may also be integral to ensuring optimal efficiency in a remote first care pathway [9].

Mixed methods were used to generate and test the hypothesis as per the COSMIN study design checklist [19]. As the ASSIST measure is based upon an existing tool, and the specific wording and questions from this have been developed and validated involving patient and clinician representatives previously, clinicians provided responses to the hypothesis generation questions [13]. This provided the perspective of aiming to summarise the prior items into a remote diagnostic measure, which would minimise ambiguity or redundancy in potential questions. As such, some of the cardinal signs and symptoms of infection were

TABLE 8 | Factor matrix extracted by maximum likelihood of estimation with two factors.

Factor matrix[a]	Factor	
	1	2
Wound drained	0.999	
Wound opened	0.705	
Operation under GA	0.704	
Superficial dehiscence		0.772
Erythema		0.653
Purulent exudate		0.6
Serous exudate		0.594
Deep dehiscence		0.558
Sought wound advice		0.541
Wound smell		0.501

Note: Extraction method: maximum likelihood.
[a]Two factors extracted. Seven iterations required.

TABLE 9 | Factor matrix extracted by maximum likelihood of estimation with three factors.

Rotated factor matrix[a]	Factor		
	1	2	3
Superficial dehiscence	0.817		
Deep dehiscence	0.682		
Purulent exudate	0.676		
Serous exudate	0.612		
Erythema	0.594		
Wound drained		0.979	
Operation under GA		0.69	
Wound opened		0.67	
Wound warmth			0.739
Sought wound advice			0.634
Antibiotics			0.523

Note: Extraction method: maximum likelihood. Rotation method: Varimax with Kaiser normalisation.
[a]Rotation converged in five iterations.

removed, such as swelling and systemic pyrexia. While integral to a holistic definition of SSI, these features would not occur in isolation or may be indicative of a non-SSI complication, leaving the possibility of diagnosis in their absence. Those identified with infection remotely could have the additional features confirmed at in person assessment where required.

Both principal components and maximum likelihood of estimation were used as methods of factor analysis. While a three-factor model appears to have the best fit, these resulted in marginally differing solutions varying between 11 and 12 items. Given the subjectivity involved factor analysis, each of the three-factor solutions will be evaluated for diagnostic accuracy and reliability in the identification of SSI. An oblique rotation was used (promax with Kaiser normalisation) given the large, combined dataset and likelihood of having some correlation between items.

This study does have some limitations. Data were collected in a tertiary vascular centre in a patient group at high risk for SSI; exploration of the final model in other contexts would be required for generalisability of findings. A hypothesis was generated a priori from five independent clinicians who then discussed and came to a consensus in line with the COSMIN guidelines [19]. Given the prior development work on item wordings and the unique context of the ASSIST measure, a wider group was not sought, and additional input from patients, community nurses and general practitioners may have provided alternative perspectives. While the initial sample ($n = 114$) was adequate to evaluate structural validity through factor analysis (at least five times the number of items, of which there were 19 and ≥ 100 participants), a combined sample ($n = 570$) ensured 'very good' outcomes as per the COSMIN guidelines; there is potential for bias in the outcomes when completed this way [19]. Results of the factor analyses did not differ when the initial sample ($n = 114$) from a single rater was evaluated.

5 | Conclusion

This study identified three potential models for a remote diagnostic measure to identify SSI that combines clinician review of patient-provided wound images and patient-reported questionnaire items. Each model is substantially shorter than the alternative available measures, which have not been designed for combined use, ensuring that this is simple and easy to use. Further evaluation of each model for reliability and diagnostic accuracy to validate a final measure is required before this approach can be implemented in routine clinical practice.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

All data can be made available at reasonable request to the corresponding author.

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