Content Validation of a Standardized Algorithm for Ostomy Care

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Abstract
The number of ostomy care clinician experts is limited and the majority of ostomy care is provided by non-specialized clinicians or unskilled caregivers and family. The purpose of this study was to obtain content validation data for a new standardized algorithm for ostomy care developed by expert wound ostomy continence nurse (WOCN) clinicians. After face validity was established using overall review and suggestions from WOCN experts, 166 WOCNs self-identified as having expertise in ostomy care were surveyed online for 6 weeks in 2009. Using a cross-sectional, mixed methods study design and a 30-item instrument with a 4-point Likert-type scale, the participants were asked to quantify the degree of validity of the Ostomy Algorithm’s decisions and components. Participants’ open-ended comments also were thematically analyzed. Using a scale of 1 to 4, the mean score of the entire algorithm was 3.8 (4 = relevant/very relevant). The algorithm’s content validity index (CVI) was 0.95 (out of 1.0). Individual component mean scores ranged from 3.59 to 3.91. Individual CVIs ranged from 0.90 to 0.98. Qualitative data analysis revealed themes of difficulty associated with algorithm formatting, especially orientation and use of the Studio Alterazioni Cutanee Stomali (Study on Peristomal Skin Lesions [SACS™ Instrument]) and the inability of algorithms to capture all individual patient attributes affecting ostomy care. Positive themes included content thoroughness and the helpful clinical photos. Suggestions were offered for algorithm improvement. Study results support the strong content validity of the algorithm and research to ascertain its construct validity and effect on care outcomes is warranted.

Key Words: ostomy, ostomy algorithm, validation study, stomal complications, peristomal complications

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A after nearly six decades and despite a recent increase in scientific studies, ostomy care and management continues to be founded mostly on “subjective and observable empirical experiences provided by clinicians.” Currently, implementation of evidence-based clinical practice is increasingly aligned with healthcare reimbursement, not only to improve care quality and patient safety, but also to help reduce medical errors, decrease waste, improve continuity across clinical settings, and make healthcare more affordable for the individual and healthcare system. Payors are no longer willing to reimburse interventions without scientific substantiation. The establishment of federal agencies such as the Agency for Healthcare Research and Quality (AHRQ), and the National Guideline Clearinghouse (NGC) is further proof of the importance of evidence-based medicine (EBM) in every clinical setting.

In 2008, the Wound Ostomy Continence Nurse (WOCN) Society (an association of nurses who specialize in the care of wound, ostomy, and continence) surveyed 1,586 of its members. The survey found that respondents spend approximately 21% of their time providing ostomy care. Due to shortened hospital stays, the majority of pre-and postoperative ostomy teaching and rehabilitation now occurs in patients’ homes or in long-term care. What is more intriguing is the current belief that the number of stomas is decreasing due to the number of sphincter-saving surgeries and technological advances now available. However, because of the rapidly aging US population, this is not a likely reality, although definitive data to substantiate this hypothesis are not available.

Due to the aging of America’s nursing population, a national nursing shortage, the small percentage of time spent on ostomy care by a small number of WOCNs, and the substantial number of patients requiring such specialized care, the majority of ostomy care is provided by non-specialized clinicians or unskilled caregivers and family. These practitioners, through no fault of their own, often lack current ostomy care skills, a working understanding of ostomy management systems, or the ability to identify and treat common stoma complications.

When stoma and skin complications are not properly identified and managed, rehabilitation is delayed, patient quality of life is diminished, and healthcare costs rise. Because “assisting in the choice of a pouching system is one of the most important contributions” involved in ostomy rehabilitation, several attempts have been made to develop clinical tools to assist non-specialized caregivers in making these crucial decisions. Unlike validated clinical algorithms for wound care, these tools lack content validation, standardized terminology, and wide integration into clinical practice across settings.

Limited evidence-based literature exists on the steps and sequences necessary to select an adequate ostomy management system for individuals with stomal or peristomal complications. A panel comprising six certified WOCN consultants, one RN, and two certified WOCN ConvaTec employees utilized ConvaTec Canada’s Canadian Ostomy Assessment Guide (COAG) existing best practice documents, WOCN Society - Standards of Care, and existing evidence-based literature to develop and refine ConvaTec’s Ostomy Algorithm. The new Ostomy Algorithm consists of 11 assessments that lead to a pathway of individualized patient management options. One of the 11 assessments (Assessment 10) is a tool that can be utilized as a stand-alone instrument for assessing peristomal skin complications. This instrument, the Studio Alterazioni Cutanee Stomali (Study on Peristomal Skin Lesions [SACS™ Instrument]), was developed and validated in Italy. The purpose of this study was to obtain content validation data for the newly developed Ostomy Algorithm from expert WOCN clinicians.

**Literature Review**

**Stoma complications.** Annually, nearly 120,000 people undergo ostomy surgery in the US and an estimated 800,000 individuals in the US live with an ostomy. Despite major advances in ostomy care and designated ostomy specialists such as WOCNs, as much as two thirds of individuals who undergo ostomy surgery will experience one or more stoma complications. These complications can significantly interfere with activities of daily living, lead to psychosocial distress, and reduce quality of life.

The actual incidence of peristomal and stomal complications is difficult to ascertain because rates reported in the literature vary widely from 6% to 66.8%. Differences in definitions, consensus of terms, populations, study design, and timing of measurements make comparisons of rates across studies problematic. A review of the literature revealed numerous studies describing different complication rates; select, relevant studies are presented to illustrate the wide range of rates reported in the literature.

In a large prospective audit of 3,970 ostomy patients, Cottam et al documented 1,329 (34%) complications (including peristomal skin-related problems) within 3 weeks of surgery. Herlufsen et al investigated the frequency, severity, and diversity of peristomal skin disorders among individuals with a permanent stoma in a community population and found that skin disorders were higher for ileostomy (57%) and urostomy...
patients (48%) than for colostomy patients (35%). Only 38% of study participants with diagnosed peristomal skin complications agreed they had a problem and more than 80% of participants did not seek professional help for these problems.

Ratliff et al.21 evaluated 220 new ostomy patients at a 2-month follow-up visit and identified a 16% peristomal complication rate. Ratliff and Donovan22 studied 161 ostomy patients seen in a 1-year period and reported a complication rate of 6% with complications highest in patients with an ileal conduit (15%) and ileostomy (9%).

In a descriptive study, Richbourg et al.,23 using a survey questionnaire mailed to individuals who had undergone ostomy surgery at their facility, identified 34 people (76%) who had peristomal skin irritation. Participants rated peristomal skin irritation as one of their top five difficulties after hospital discharge. Wood et al.24 followed patients with an ileal conduit for up to 63.4 months after surgery and reported an overall stoma complication rate of 34.4%; in addition, re-operation was required in 24.7% of the total patient population due to parastomal hernia and stoma retraction.

Salvadalena16 conducted a systematic review and identified 21 studies published between 1990 and 2007 that measured the incidence of stomal and peristomal complications. Due to differences in study design, operational definitions, and timing of measurements, Salvadalena concluded it is not possible to pool data and measure the incidence of stomal and peristomal complications. Variability in study designs and absence of operational definitions were identified as major problems among the studies. Research targeting these problems is necessary to investigate challenges encountered by ostomates postoperatively.

**Stomal/peristomal assessment instruments.** Bosio et al.12 conducted a prospective, observational study between 2003 and 2006 across eight ostomy centers in Italy. Patients were divided into two groups according to onset of complications (less or greater than 1 year). Peristomal skin was assessed at 0, 4, 12, and 24 weeks. Peristomal skin complications were identified in 339 of 656 ostomy patients (52%, 272 men and 67 women). From the data obtained in this study, a classification scheme based on recurrent clinical manifestations (lesions) and topographical location was created and the SACS™ Instrument was developed by seven enterostomal nurses and four surgeons from eight facilities in Italy. The five most common lesions (L) observed in the Bosio study and included in the instrument are hyperemic lesion (peristomal skin reddening without loss of substance), erosive lesion with loss of substance not extending beyond the dermis, ulcerative lesion extending beyond the dermis, ulcerative fibrositic/necrotic lesion, and proliferative lesions (granulomas, oxalate deposits, neoplasm).12 Skin lesion severity is assessed on a scale of I to X — eg, LI for less severe and LX for more severe skin complications. Five topographical (T) location quadrants are used to document peristomal lesion location.

The criteria used in the instrument are universally familiar in that L is similar to wound depth description and T to that of the grid used to help locate lesions in breast cancer patients (see Figure 1). The instrument reduces the subjective assessment of peristomal skin lesions and promotes a universal language for communicating peristomal skin disorders. However, the SACS™ Instrument only addresses one component of ostomy clinical decision-making and a broader instrument, such as an algorithm, is needed to address all aspects of the management of stomal and peristomal complications.

In another effort to provide clinicians with a classification system for peristomal skin complications, the Ostomy Skin Tool was developed by a group of 12 ostomy care nurses from around the world in collaboration with an ostomy products manufacturer. The Ostomy Skin Tool is comprised of two sections. Part One is used to calculate a score that describes the peristomal skin condition and incorporates both the area affected and severity of the problem. Part Two is a diagnostic guide that provides classification of peristomal skin complications according to clinical assessment and standardized descriptions.25 Content validity of the tool, the Coloplast Dialogue Study, is in progress.26

In an effort to establish valid, reliable definitions for stomal and peristomal complications, Colwell and Beitz15 surveyed 686 WOCNs to elicit their evaluation on the proposed definitions. On a scale of 1 to 4, the mean score for all definitions and interventions was 3.64 (SD = 0.30) and the overall survey’s Content Validity Index (CVI) was .91, demonstrating a high consensus.

The definitions proposed by Colwell and Beitz, along with use of the SACS™ Instrument, may offer clinicians a common language and objective way to diagnose and classify peristomal skin complications.7 Universal adoption of both also will allow clinicians to accurately measure the prevalence and incidence of peristomal and stomal complications; both the definitions and the SACS™ Instrument have been content validated but must be tested with real patients for full validity and reliability. Ultimately, this may help WOCNs expand the integration of evidence into practice and lead to improvements in the quality of care for the individuals living with an ostomy.

**Algorithms and content validation.** Algorithms are graphic care maps that allow users to visualize major cognitive components and processes of a clinical problem; they enable the clinician to complete a stepwise evaluation of a specific issue.27 From a metacognitive perspective, algorithms help organize thinking, make relationships more meaningful, and highlight crucial decision points.28

Most algorithms and decision maps in healthcare are not research-based and lack a data-driven evidence base to support their efficacy. Typically, they only have face or preliminary content validity, the lowest level of evidence (see Table 1). Establishing content validity is necessary for any instrument, especially for algorithms or decision pathways affecting patient safety. Establishing content validity helps ensure the components and information included adequately reflect the domain of content critical for inclusion (eg, ostomy care); this rigorous two-stage process is based on development and judgment quan-
Ostomy Algorithm Development and Content Validation

Preliminary face validity, a component of the development stage, of the Ostomy Algorithm was established by nine WOCNs with extensive ostomy experience (seven WOC nursing consultants and two WOCN ConvaTec employees) who specified critical aspects of ostomy care with a focus on peristomal complications and the SACS™ Instrument. Through several focus-group style meetings, components of ostomy care were delineated and sequenced in terms of normal care. The final version of the Ostomy Algorithm was developed with each of the 11 critical components on a separate page (see Figure 2a,b). Definitions and associated pictures or visuals of subcomponents were included along with possible recommended management options. The user can circle the option and know which type of product/choice may be appropriate to use for the patient being assessed. All participants repeatedly reviewed and revised the algorithm.

The second stage, judgment quantification, entails asking a larger number of experts to evaluate the validity of individual components and the total instrument. The current study provided additional data based on a nationally representative sample of ostomy care experts.

Judgment quantification can be established using the CVI in a process developed by Waltz and Bausell and modified by Lynn. The ostomy experts rated each component of the algorithm using a 4-point Likert-type scale. For this study, the rating scale was modified for clarity to read: 1) Not relevant/Not important; 2) Unable to assess relevance/importance without revision; 3) Relevant/important but needs minor alteration; and 4) Very relevant/very important. The CVI is based on the proportion of components in the algorithm that are rated by participants as 3) Relevant but needs minor alteration or 4) Very relevant/very important. Perfect agreement would yield a CVI of 1.0. For most purposes, CVIs rated ≥ 0.8 are considered a high level of endorsement of content validity. Inflation of
the CVI was controlled by including a large group of ostomy experts. Opportunity to comment on the Ostomy Algorithm components and overall algorithm construction was provided. Narrative comments were analyzed for themes of strengths and concerns.

In addition to content validity, the nine WOCN experts also reviewed the Ostomy Algorithm to evaluate its readability. Berk35 suggests that instrument components (eg, items) should be reviewed by the panel of experts for readability and the possibility of offensive language or obscure references.

**Research objectives.** The objective of the research was to determine content validity of a newly developed Ostomy Algorithm.

**Research questions.**
1) How do ostomy experts rate the critical ostomy care components and decision/descriptive processes inherent in the Ostomy Algorithm?
2) What is the overall CVI and for critical ostomy care components and decision/descriptive processes inherent in the Ostomy Algorithm?
3) What themes of positive responses or concerns about appropriateness/usefulness of the Ostomy Algorithm do ostomy care experts describe?

**Methods**
A cross-sectional, online, quantitative mixed methods survey design with qualitative components was used. An independent, third-party survey firm hired by the development company conducted the research among WOCNs. Participants were blinded to company sponsorship to avoid possible assent-biased or socially undesirable responses. The survey was conducted for 6 weeks (from July 30 through September 14, 2009). Participants were fully informed about the purpose of the study and given the opportunity to decline participation after explanation.

**Sample and setting.** The initial target for sample size was 200 WOCNs; 180 were recruited. This figure was still above the 150 suggested minimum number of participants needed for power analysis even though this was a nonexperimental study. Study participants met the following inclusion criteria: experience in ostomy care (more than 2 years); formal education in ostomy care (WOCN, ET, or COCN); written and reading ability in English; practice in a hospital, medical center, home health agency, outpatient clinic, rehabilitation center, and/or nursing home.

**Instruments.**

**Ostomy Algorithm.** The Ostomy Algorithm is designed to help the healthcare provider make evidence-based decisions for managing a fecal or urinary stoma. When used appropriately, the expected outcomes of the algorithm include:
- Selection of a pouching system that provides secure, predictable comfortable wear time;
- Maintenance of intact peristomal skin;
- Effective prevention, identification, and management of commonly identified peristomal complications;
- Effective identification and management of commonly identified stoma complications.

The Ostomy Algorithm is comprised of 11 assessments critical to achieving the previously stated outcomes (see Table 2). For example, in Assessment 1 (Type of Ostomy), the user is asked to identify whether the patient has a colostomy, urostomy, or ileostomy. The steps or choices within each assessment were

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Content validity</td>
<td>Extent to which an instrument or method of measurement includes all the major components pertinent to the construct being measured. It is present when the choice and importance of instrument components are appropriate for the instrument’s purpose</td>
</tr>
<tr>
<td>Construct validity</td>
<td>Degree to which an instrument, test, or scale measures or addresses what it is supposed to measure or target. Construct validity is currently considered a broad evaluation of measurement that includes content, face validity, and the like</td>
</tr>
<tr>
<td>Face validity</td>
<td>An instrument or scale “looks” valid — that is, it gives the appearance of measuring the content or area that it is supposed to measure; the instrument looks “reasonable”</td>
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**Table 1. Types of validity: definitions**

Other forms of validity commonly described include discriminant, concurrent, predictive, and convergent/divergent. They are not used in this study.

ALGORITHM FOR OSTOMY CARE

ASSessment 1: Type Of Ostomy

**Colostomy:** A surgically created opening into a portion of the colon (large intestine). Colostomy output varies from liquid to formed stool, based upon the portion of the colon involved.

**Ileostomy:** A surgically created opening into the ileum (portion of the small intestine). Ileostomy output varies from pasty to liquid stool.

Choose appropriate management options on ostomy management plan:

1. Consider option 2 if output liquid
2. Consider option 3 if output liquid
3. Consider options 3 or 4 if output liquid and/or high volume

**Urostomy:** A surgically created opening into a portion of the urinary tract. Stomal output is urine. Urostomies can be created either by a direct opening into a portion of the urinary tract, i.e., ureteroostomy, vasovasostomy, or by diverting the urine away from the bladder through a piece of intestine, i.e., ileal conduit or colon conduit.

Choose appropriate management options on ostomy management plan:

3. Consider options 3 or 4 if output liquid and/or high volume

ASSESSMENT 1: TYPE OF OSTOMY

1. **Drainable Pouch:** A pouch with an opening at the bottom. This opening is wide enough to empty solid stool. A clamp or integrated closure is used to keep the pouch closed until it is time to empty.
2. **Closed End Pouch:** A pouch without an opening or clamp at the bottom (also known as a non-drainable pouch). It must be removed when one-third to one-half full.
3. **Urostomy Pouch:** A pouch with a spout (or tap/spigot) at the bottom used for emptying or connecting to bedside drainage. Originally designed for people who need a pouch to contain urine, this pouch may also be used as an option for people who have very liquid stool, such as those with an ileostomy.
4. **One-Piece Pouching System:** The skin barrier and pouch are fused when the pouch system is manufactured. One-piece urostomy and fecal pouches are also available.
5. **Two-Piece System:** A two-piece pouching system with a flange is one whereby the skin barrier and pouch are manufactured separately with rigid to semi-rigid rings or adhesive flanges, which allow the user to attach the two parts. Two-piece urostomy and fecal pouches are available.*

* Consider patient’s vision, dexterity, and personal preference when selecting options 4 or 5.

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Figure 2a,b. Sample screens from validation survey with options for this assessment step.
developed over several years (beginning in 2007) by WONC experts following extensive literature review, including best practice documents published by professional societies. By May 2009, the Ostomy Algorithm was ready for content validation.

**Ostomy Algorithm Questionnaire.** To test the structure and processing of the Ostomy Algorithm, statements rating content validity of critical components and subcomponents of the algorithm were developed. For example, participants were presented with the statement, “Relevance/importance in assessing patient’s stoma type in choosing a pouch type” (ie, drainable, closed end, and urostomy) and asked to rate level of agreement with the relevance (importance on a scale of 1 to 4 where 1 = Not relevant/Not important and 4 = Very relevant/very important). The resultant validation questionnaire was 30 statements to which participants responded using the previously described rating scale process described by Lynn and modified by Colwell and Beitz. The questionnaire also allowed for open-ended, write-in comments about algorithm components and/or the overall process. Comments were mandatory if a rating of 1 or 2 was given. Participants were asked to consider adding comments regarding omissions, suggestions for improved clarity/succinctness/importance, and possible alternatives.

**Procedure.** ConvaTec Inc. acquired the services of an independent survey firm to place the Ostomy Algorithm survey into an online format in June 2009. Recruitment emails were sent out to email addresses of the WOCN Society and to WOCNs on the company’s email list. In addition, recruitment postcard mailers were sent out to persons on the WOCN Society list. Participants also were recruited via direct calling methods following the email blast and postcard mailers. Once eligibility was verified and the potential participant agreed to participate following complete disclosure of the study purpose, participants’ email addresses were collected and participants were sent a link to take the online survey.

Participants viewed screenshots that place an individual assessment of the algorithm and corresponding management options side-by-side for review. Then, participants were asked to read and answer (rate) each assessment component and its associated management option. The survey took approximately 25 minutes to complete. Each participant received $30.00.

**Ethical considerations.** A description of the proposed study was submitted for medical review and deemed exempt from Institutional Review Board (IRB) review due to lack of human subject interventions and low risk of the study (WOCNs routinely manage stomal and peristomal care issues). Participants agreed to take part in the online survey after an introductory explanation of the study.

**Data analysis.** Demographic data, respondents’ ratings of the algorithm components, and comments to open-ended questions were collected by the third party conducting the study. Quantitative data were uploaded into an Excel 2007 spreadsheet with statistical analysis capabilities and Quantum™ was used to calculate frequencies. Summary statistics were calculated for the demographic data. Mean scores for ratings were derived for each component of the 30-item survey (algorithm components) and for the total algorithm itself. The CVI was calculated by grouping items rated 1 and 2 and items 3 and 4. The proportion of items rated 3 and 4 then was calculated for the entire instrument and for each algorithm component. Responses to open-ended areas were thematically organized for positive and negative comments. Using qualitative data reduction techniques, themes and associated indicator statements were identified.

**Results**

**Participants.** A purposive sample of 166 WOC registered nurses (also CWONs, ETs, and COCNs) who self-identified as spending at least 30% of their time treating ostomy patients and were familiar with peristomal skin issues in these patients participated in the online survey. Among participants, 97% were CWOCNs or ETs and 3% were COCNs; 53% practiced solely in acute care; 20% practiced in post acute care (home care and the like) only, and 27% practiced in both settings. Participants’ healthcare facility size varied across the group: 25% practiced in facilities with >500 beds, 31% practiced in facilities with 301 to 500 beds, 41% in facilities of 100 to 300 beds, and 3% in facilities of <100 beds.

Participants were mostly female (97%) and varied in age. The average age was 50 years, with age distribution as follows: 65 years and older (3%), 64 to 55 years (29%), 54 to 45 years (46%), 44 to 35 years (18%), and 34 to 25 years (4%). On average, participants treated four to five new ostomy patients per week. Participants also were experienced clinicians: 28% had 20 years or more of clinical practice, 28% had 10 to 20 years’ experience, and 43% had 2 to 10 years.

Participants in the sample hailed from 40 of the 50 states; by region, they represented the Northeast (28%), South (28%), Midwest (32%), and West (11%).

The participants’ educational level was not collected in the demographic section because WOCNs have had minimum BSN level requirements since the early 1980s. Currently, 94% of WOCNs hold a BSN or MSN degree or higher. Therefore, collection of this data component would not have added markedly to study results.

The demographic characteristics of the sample were similar to WOCN characteristics nationally. In the 2008 WOC Nursing Salary and Productivity Survey, demographic data analysis showed that 96.4% of WOCNs are female, 49.2% are in the 50 to 59 year old group, 24% have between 10 to 20 years of WOC nursing experience, and 56.2% practice primarily in acute care.

**The algorithm.**

**Ostomy care components.** The mean rating of all ostomy care components and decision/descriptive processes inherent in the Ostomy Algorithm, research question 1, was 3.8 (out of 4). Verbatim responses supported numeric ratings in that no omissions of critical assessment components were identified. Comments regarding nuances to the decision-making process inherent in the algorithm mostly involved individual patient
The overall CVI for critical ostomy care components and decision/descriptive processes inherent in the Ostomy Algorithm, research question 2, was .95, (out of 1). For most purposes, a CVI of ≥0.8 is considered a high level of endorsement of content validity.32 The assessment with the highest content validity score (.98) was Assessment 7, “Level Pouching Surface” (the area surrounding the stoma where the skin barrier will adhere). This was followed by Assessment 4 (.97) “Stoma Profile” and Assessment 11, “Presence/Absence of Peristomal Skin Complications” (.97). The CVI results indicate a high level of relevance/importance of these particular assessments by the WOCN experts. Even individual assessments with lower scores fell within acceptable range for content validity, with scores ranging from .90 to .96. These aspects include Assessment 3 (“Stoma Type” [.90]), Assessment 5 (“Stoma Shape” [.90]), and Assessment 1 (“Type of Ostomy” [.92]) (see Figure 2). No rating differences based on clinical setting, percentage of time spent on ostomy care, or years in practice were noted (see Table 2).

Comments. Several themes of positive responses/concerns about appropriateness/usefulness of the algorithm emerged from the ostomy care experts’ comments (research question 3). The Ostomy Algorithm was generally well received (see Table 3).

Table 2. Mean overall instrument and individual component ratings and content validity index (CVI) scores

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Mean score</th>
<th>Content validity index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall algorithm</td>
<td>3.8</td>
<td>0.95</td>
</tr>
<tr>
<td>Assessment 1: Type of Ostomy</td>
<td>3.7</td>
<td>0.92</td>
</tr>
<tr>
<td>Assessment 2: Type and Volume of Output</td>
<td>3.81</td>
<td>0.95</td>
</tr>
<tr>
<td>Assessment 3: Stoma Type</td>
<td>3.59</td>
<td>0.90</td>
</tr>
<tr>
<td>Assessment 4: Stoma Profile (Stoma Protrusion)</td>
<td>3.86</td>
<td>0.97</td>
</tr>
<tr>
<td>Assessment 5: Stoma Shape</td>
<td>3.61</td>
<td>0.90</td>
</tr>
<tr>
<td>Assessment 6: Abdominal Contour</td>
<td>3.8</td>
<td>0.95</td>
</tr>
<tr>
<td>Assessment 7: Level Pouching Surface</td>
<td>3.91</td>
<td>0.98</td>
</tr>
<tr>
<td>Assessment 8: Presence/Absence of Devices</td>
<td>3.84</td>
<td>0.96</td>
</tr>
<tr>
<td>Assessment 9: Presence/Absence of Stoma Complications</td>
<td>3.83</td>
<td>0.96</td>
</tr>
<tr>
<td>Assessment 10: Peristomal Skin Assessment (SACS™)</td>
<td>3.75</td>
<td>0.94</td>
</tr>
<tr>
<td>Assessment 11: Presence/Absence of Peristomal Skin Complications</td>
<td>3.87</td>
<td>0.97</td>
</tr>
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</table>

Table 3. Representative participant comments

- “This would be an invaluable tool for staff nurses. It is quite detailed and would need some educational program from the WOCN as an introduction. It would be great for nurses on shift when the WOCN is not available.”
- “Well done. Would be interested in using tool to teach other nursing staff.”
- “I think that the algorithm will be a very useful tool for the bedside clinical nurse. I would like to see it (the algorithm) published so clinical nurses can use it, especially when CWOCN is not available.”
- “…Illustrations are great! The pictures of the descriptions were the BEST I have ever seen. The descriptions, causative factors were very inclusive, and easy to follow. Great job! Super tool to use for ANY practitioner!”
- “Excellent coverage of how to appropriately assess the origination of the stoma, assessment of the stoma and the peristomal skin when choosing the optimal pouching system for the ostomate. Great photos.”
- “I would use this tool to teach my staff…highly organized…would use it no matter what company issued it…would use it as it is if it was available. Nice job! ...”

and nurse factors as well as clinical tips gained from actual clinical practice.

The overall CVI for critical ostomy care components and decision/descriptive processes inherent in the Ostomy Algorithm, research question 2, was .95, (out of 1). For most purposes, a CVI of ≥0.8 is considered a high level of endorsement of content validity.32 The assessment with the highest content validity score (.98) was Assessment 7, “Level Pouching Surface” (the area surrounding the stoma where the skin barrier will adhere). This was followed by Assessment 4 (.97) “Stoma Profile” and Assessment 11, “Presence/Absence of Peristomal Skin Complications” (.97). The CVI results indicate a high level of relevance/importance of these particular assessments by the WOCN experts. Even individual assessments with lower scores fell within acceptable range for content validity, with scores ranging from .90 to .96. These aspects include Assessment 3 (“Stoma Type” [.90]), Assessment 5 (“Stoma Shape” [.90]), and Assessment 1 (“Type of Ostomy” [.92]) (see Figure 2). No rating differences based on clinical setting, percentage of time spent on ostomy care, or years in practice were noted (see Table 2).

Comments. Several themes of positive responses/concerns about appropriateness/usefulness of the algorithm emerged from the ostomy care experts’ comments (research question 3). The Ostomy Algorithm was generally well received (see Table 3).

Qualitatively, the WOCN experts provided a total of 880 comments, which were examined for common themes and trends and categorized for summarization. Based upon the volume and nature of comments, it was sometimes difficult to determine if the respondents’ comments focused on the study process or the algorithm content. This difficulty was especially true of some of the comments on the algorithm format as well as the overall comments because the comments were too global and did not specify particular issues.

Patient orientation. Notably, many comments related to the use of the SACS™ Instrument and the “orientation” or the way the nurse is viewing the patient and stoma to assess the peristomal skin lesions. The majority of the respondents typically use a “clock face” orientation when assessing patients, wounds, and anatomical locations. Participants felt the orientation used
in the SACS™ Instrument (quadrants) should be changed to maintain their commonly used practice of using the clock face for orientation and anatomical position, which is patient’s right or left.

Clinical judgment. Many comments related to the use of clinical opinion/judgment. The respondents are clinical experts and the comments indicated that often more than one solution can provide the intended outcome to a clinical problem and depends on the clinician’s preference. Additionally, many respondents commented on the importance of individual patient attributes that affect decision-making such as patient preference and physical and emotional limitations. Many who identified these issues also commented that the decision-making process is complex and the experience level of the nurse affects this process. Not all variables contributing to the final patient outcomes can be expressed in an algorithm.

Algorithm format: Algorithm format also was an important issue. Some respondents felt the overall format could be confusing for users and would require training for basic level practitioners to use the algorithm correctly. Positive comments about the current format included affirmation of the clinical photos and overall thoroughness of the content. Issues that were identified for potential improvement included positioning the algorithm and management options side-by-side for easy comparison and reducing the verbiage in some areas. Additional comments focused on providing expanded clinical choices/interventions for certain problems, the complexity of the algorithm, and the target clinicians who would find it most useful in their practice. Based upon an evaluation of respondents’ comments, minor amendments to the algorithm will need to be made before implementation.

Discussion

As the momentum for evidence-based practice accelerates, the need for standardized language and validated tools for ostomy care becomes compelling. The Ostomy Algorithm was designed to provide healthcare professionals with a heuristic (experience-based techniques that help in problem solving, learning, and discovery) device for providing evaluation and management options for individuals living with an ostomy. Based on the content validation study results, the Ostomy Algorithm was very well received by expert WOCNs and the number of persons willing to participate in the survey (n = 166) suggests a clear need for this instrument.

Content validity is mandatory for any algorithm that affects patient safety and provides a basis for best clinical practice. The strength of the overall content validity score (.95) is well above the acceptable score of .7 to .8. The highest content validity scores for Assessment 7 (“Level Pouching Surface” [.98]), Assessment 4 (“Stoma Profile” [.97]), and Assessment 11 (“Presence/Absence of Peristomal Skin Complications” [.97]) were noted as priority issues when identifying problem-causing areas. Even the lowest content validity scores (Assessment 3, “Stoma Type” and Assessment 5, “Stoma Shape” [.90]) were well above the acceptable rate.

No other published studies describing an evidence-based, content-validated algorithm or including recommendations for peristomal skin complications and specific documentation locators were identified. Currently available instruments such as The Coloplast Ostomy Skin Tool do not address stoma care management. An evaluation of the COAG tool demonstrated major benefits for ostomy patients when non-specialized nurses use the guide to select an appropriate pouching system. Education and training were important when using COAG.

Much like the Solutions® Algorithms for Wound Care that address wound care management and options, the Ostomy Algorithm can help in comprehensive patient management by providing an organized system for patient assessment and care, which may improve self-confidence and quality of life. A list of definitions accompanying each section enhanced the Ostomy Algorithm and specified each description, allowing for more accurate future data collection.

Resultant changes. Based on an extensive review of the 880 qualitative comments provided, the following algorithm changes have been planned before implementation:

1. Each of the 11 assessments was viewed one screen at a time but participants inferred an appreciation of the interplay necessary among the assessments to create the overall clinical picture. Therefore, a general statement will be added, describing how algorithm assessment decisions help refine the clinical decision making process and build toward the end result of an effective ostomy management plan. A statement also will be added to clarify that many of the listed management options may be appropriate for more than one assessment.

2. An oversight was identified within Assessment 2: Type and volume of output. “Extended wear skin barriers” were mentioned in the test question but not identified within the algorithm itself. Extended wear skin barriers will be added as a management option and defined in the glossary appropriately.

3. Non-stoma related variables were identified as important considerations for at least half of the Algorithm assessments. Issues such as patient preference, dexterity, and visual acuity were noted to be essential to the selection of an adequate ostomy pouching system. A statement about the effects of unique considerations on the clinical decision-making process will be added to the introductory section of the algorithm.

4. A minimum of 50 comments stated that although the content was appropriate, the text was “too wordy.” The algorithm will be reviewed and edited to shorten and limit text to bullet points.

Many respondents commented on the benefits of using this instrument to teach clinical staff.

Given the limited number of ostomy specialists in the hospital, home care, long-term care, and outpatient settings, staff in all settings could benefit from using the Ostomy Algorithm.
In addition, having/using standardized language could be a valuable resource to help improve communication across the continuum of care. Furthermore, use of a valid ostomy algorithm may reduce the frequency and cost of trial-and-error use of multiple products while increasing patient comfort and quality of life.

Limitations

Some limitations were noted in the study. Survey participants were not asked about their level of education or if they were certified in ostomy care. All respondents self-identified as experts in the field of ostomy care but this expertise could not be clinically validated. Another limitation related to the qualitative aspects was that participants typed in their comments online and no opportunity existed for follow-up questioning or scrutiny of participants’ meaning. In addition, this study was conducted only in the U.S.—future research is needed to determine the validity of the algorithm in other countries, although the SACS™ Instrument was content validated in Italy. The Ostomy Algorithm has not been clinically validated with real-life stoma complications or among nonexpert users. Future research should target the development of this construct validity component and assess the effect of algorithm implementation on patient outcomes.

Conclusion

Both quantitative and qualitative study results support the strong content validity of the new Ostomy Algorithm and suggest the potential of this algorithm to help provide optimal patient care and facilitate standardization of ostomy care and documentation. Future research should target the instrument’s role in facilitating objective, standardized, evidence-based decisions concerning management of stomal and peristomal skin complications for persons living with an ostomy as well subsequent patient outcomes. A construct validation study to test the algorithm for use by staff nurses is planned.

References