

(53%). Fear of pouch leakage kept 47% of the sampled ostomates from leaving their homes 1 or more times per week. The authors concluded that pouching problems can affect the person with an ostomy in multiple ways including repeated exposure of the skin to effluent, which leads to painful skin damage, increased supply costs resulting from the appliance being changed more frequently, and stressful life events such as leakage, odor, and pain, which may contribute to depression.

The stresses of living with an ostomy can negatively affect quality of life. Because an ostomy requires intact skin to ensure adherence of a well-fitted pouch to contain odor and effluent, peristomal skin complications interfere with the pouch adherence and can negatively affect patient adjustment. This observation was noted by Maydick-Youngberg,¹³ who reported on the relationship between quality of life and peristomal skin complications. Findings suggest that the majority of people with a peristomal problem reported allergic contact dermatitis (32.3%), and of these, 12% reported irritant contact dermatitis. Overall, the average quality-of-life scores were significantly lower in participants who reported a history of irritant contact dermatitis compared to those who did not, supporting that peristomal complications are problematic and need attention to determine the best ostomy pouching system. The author recommended that with assessment of the patients' skin types, stoma output, frequency of changing the skin barrier, and knowledge of proper skin barriers, peristomal skin issues can be reduced, specifically through a secure seal to prevent leakage.

The purpose of this article is to describe the consensus-building process used to identify key factors in assessing body and stoma profiles and report the consensus outcomes. These outcomes, in the form of practice guidelines, provide expert guidance on how to assess body and stoma profiles, engage and educate patients, and suggest when to follow up with patients after hospital discharge or product change.

METHODS

The project was designed using a Modified Delphi Consensus-Building Process which was developed and led by an International Association of Facilitators, Certified Professional Facilitator KB. Funding was provided by Coloplast A/S (Humlebaek, Denmark). The Modified Delphi Process includes elements of traditional Delphi survey methodology,¹⁴ Nominal Group Technique,¹⁵ and Process Facilitation.¹⁶

Literature Review

The process started with an expert panel of 6 international ostomy nurses (authors) that determined the objectives, reviewed the literature, and developed the research questions. The expert panel held a combined face-to-face and virtual meeting with the 15-member international stoma care expert review group (Table 1) to refine the objectives and study questions and to approve the overall study methodology (Figure 1) and design. The expert panel was selected using the following criteria: experience with the consensus process, level of experience, interest, availability and was compromised of an existing institution of a global group of highly experienced enterostomal therapy nurses and wound, ostomy and continence nurses. The literature search was conducted using the following terms: convex; pouching systems; best practice, aged; case report; Crohn's disease; surgery; equipment design; female; instrumentation; stomas; bandages; standards; drainage; nursing;

TABLE 1.
International Expert Review Group

Ostomy Nurse Expert	Location of Practice
Birgitte Dissing Anderson	Denmark
Daniele Chaumier	France
Janice Colwell	United States
Werner Droste	Germany
Jane Fellows	United States
Grethe Vendelbo	Denmark
Anne Steen-Hansen	Denmark
Doris Kost	Germany
Louise Forest-Lalande	Canada
Lina Martins	Canada
Svatava Novakova	Czechoslovakia
Rosalind Probert	Australia
Sarah James-Reid	United Kingdom
Oirda Samai	France
Chantal Tielemans	Belgium

equipment design; health services needs and demand; activities of daily living; aged; attitude to health; drainage; equipment design; equipment failure; humans; ileostomy; male; middle aged; nursing methodology research; quality of life; questionnaires; nonparametric; ballooning; filter; aftercare; candidiasis, cutaneous; prevention and control; causality; colostomy; dermatitis, irritant; etiology; prevention and control; health services needs and demand; hernia, abdominal; epidemiology; etiology; humans; adverse effects; length of stay; multivariate analysis; nursing assessment; ostomy; adverse effects; patient education; prevalence; prospective studies; skin; injuries; skin care; urinary diversion; epidemiology; wounds and injuries; standards, guidelines, adhesive, assessment; ostomy; instrumentation; patient selection; and risk factors. Seventy-seven articles were included in the literature review.

Group Consensus Method

Structured group facilitation processes were used throughout the face-to-face and virtual dialogues including solution-focused dialogue,¹⁷ dynamic systems approach,¹⁸ and focused conversation¹⁹ methodologies. The independent facilitator led all group dialogues to ensure outcome-based and balanced conversations were achieved where all group members had equal say in decision-making and all ideas were heard and thoughtfully considered. The project worked toward 100% consensus for all processes used in the development of the practice guidelines by asking participants (review group and panel) whether they agreed with the practice guidance. If 100% consensus was not reached, the interactive dialogue continued until 100% agreement was obtained. This ensured all issues were examined in detail and dissenting opinions were given full consideration. This resulted in the review group and panel defining questions, determining timelines, developing the survey, and interpreting results.

Survey Processes

The first Delphi survey was created, available in 11 different languages (Table 2), and sent to ostomy nurses around the

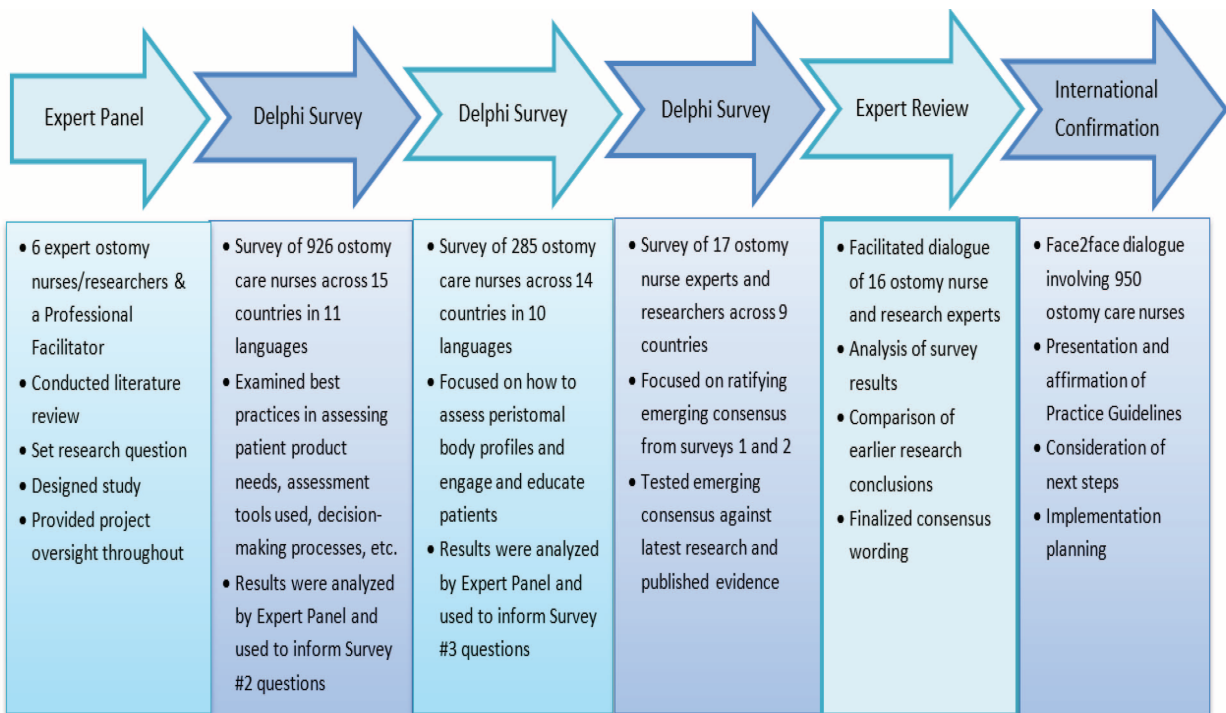


Figure 1. Modified Delphi research methodology to reach international consensus on assessment of peristomal body profiles.

world from national Listservs and nursing association mailing lists such as the Wound, Ostomy and Continence Nurses Society as well as lists developed by ostomy product manufacturers. We were unable to determine the number of surveys sent because the Listservs and mailing lists owners sent out the survey directly to their constituents. The survey was distributed in this way to ensure maximum global penetration and participation

and to meet the requirements of various national privacy laws. The first survey in process stage 1 was responded to by 926 ostomy nurses. All survey responses were anonymous. Participants were all experienced ostomy nurses providing care in home, outpatient, and hospital settings. Sixty-eight percent of respondents provided ostomy care for more than 10 years, 59% worked more than 30 hours per week providing nursing care, and close to 50% of their work involved specialized ostomy care (Figure 2). The language responses in order of prevalence by process stage appear in Table 2.

TABLE 2.
Language Responses in Order of Prevalence by Process Stage

Process Stage 1 Survey 1 (n = 926)	Process Stage 2 Survey 2 (n = 285)	Process Stage 3 Ostomy Days Dialogue (n = 960)
English	Dutch	Italian
French	French	Spanish
Japanese	English	German
Dutch	Czech	English
Czech	Japanese	French
Swedish	Swedish	Dutch
Danish	Danish	Russian
Italian	Italian	Portuguese
Norwegian	Norwegian	Danish
German	Finnish	Chinese
Finnish		Korean
		Finnish
		Czech
		Swedish
		Slovak
		Japanese

The survey comprised 25 questions and covered best practices in assessing patients' body and stoma profiles, product needs and preferences, tools used to assess quality of life and skin integrity, and topics derived from the literature review. The survey asked respondents about issues they considered in decision-making for management of the patient with a stoma and their use of the body and skin profiles and stoma assessment. The body and stoma profile assessment is a systematic process used to evaluate the area around the stoma (regular, inward, or outward shaped), the softness of the peristomal area (soft or firm), irregularities of the peristomal area (creases/folds), location of the stoma when bending, and the position of the stoma opening (skin level, above or below skin level).²⁰ The survey also explored patient engagement, patient education, frequency of patient follow-up, what practice guidelines if any, were utilized, and how patient quality of life factored into product choice and decision-making.

Results from survey 1 were analyzed by the panel and review group during a series of virtual dialogues utilizing an affirmative facilitation methodology,²¹ and a second survey (process stage 2) was created. This second survey resulted in a response rate of 30% (n = 285; all responses were anonymous). Results from survey 1 and 2 were analyzed and a 3rd survey was sent to the panel and expert review group to test the consensus results against the literature. Results from all 3 surveys were then presented to the panel and expert review group at a face-to-face

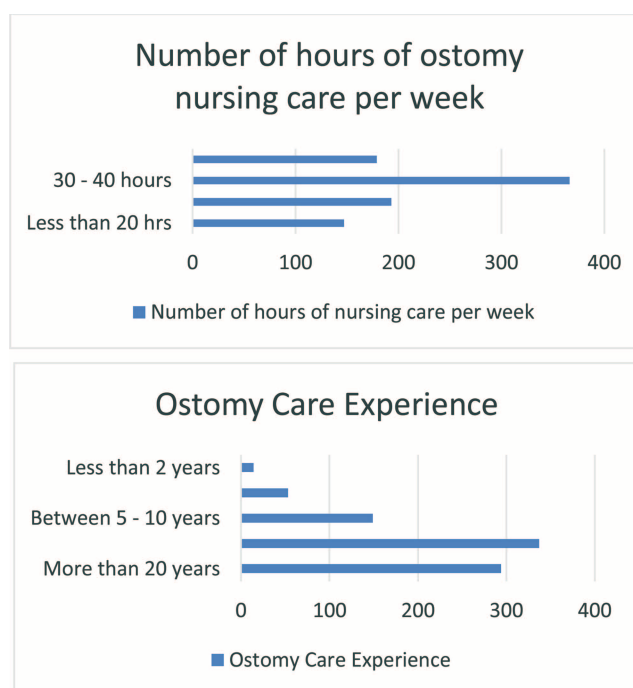


Figure 2. Ostomy experience of survey 1 respondents (n = 926).

meeting where the resulting consensus was translated into a set of practice guidelines. The practice guidelines were presented to 960 ostomy nurses at Ostomy Days, an international education program hosted by Coloplast in Copenhagen, April 2018. Ostomy nurses from 27 countries were present, including countries who were not part of the Delphi survey process, like China and Spain. The 960 nurses ratified the practice guidelines and then participated in a facilitated dialogue to reach consensus on how to implement, operationalize, and educate others on the practice guidelines. The sample sizes for each process stage and languages are reported in Table 2.

Data Management and Analysis

Survey data were combined as a total sample, included 1225 individual responses, were analyzed using *SPSS Statistical Software* (Statistical Package of Social Science, Armonk, New York), and results reported as means and medians. Themes such as coping mechanism were derived from narrative data using thematic analysis, which is a process of identifying patterns or themes within the data. Analysis by geography was not possible due to the anonymity of survey responses. Given that participants were able to choose the language in which to respond to the survey, analysis by language group did not necessarily correspond to geographic boundaries or regions.

Ethical Considerations

Institutional Review Board (IRB) approval was provided without qualifiers by Acentral IRB. All surveys were 100% anonymous, with no way for survey responses to be linked to respondents. Demographic information collected focused on clinical credentials and type of clinical practice. No individual patient information was collected. While Coloplast A/S was the sponsor and funded the study, the research questions, project oversight, and resulting consensus-based practice guidelines were created by the expert panel and international review groups, independent of the sponsor. Coloplast products

were not mentioned in the surveys or in communication with participants. The resulting guidelines do not reference or recommend any particular product; rather, they focus on how to assess and utilize the type of pouching system best suited for the patient.

RESULTS

The outcome of the consensus process identified key factors to be considered when helping the person with an ostomy determine the best product choice (Figure 3). Consensus was reached on overall principles, identification of patient assessment guidelines as well suggestions about patient engagement, education, and the frequency of contact with an ostomy care provider.

Principles That Guide Patient Assessment

1. Pouch security and peristomal skin health
 - a. 72% (667/926) of respondents indicated that pouch seal security and maintaining peristomal skin integrity were the most important factors in decision-making when determining product choices.
2. Assessment of body profile
 - a. 94% (267/285) of respondents stated that body and stoma profiles should always be assessed when choosing an ostomy product.
3. Product choices
 - a. 95% (271/285) of respondents indicated assessment of the patient's body and stoma profiles can help determine which product will provide patients with the highest level of confidence and security.
 - b. 65% (602/926) of respondents reported that the most common reasons for a product change (a new product) are pouch seal leakage and peristomal skin complications.

Patient Assessment Guidelines

1. Assess the peristomal area using a validated body profile assessment tool²² for:
 - regular, inward, or outward
 - uniform or variable
 - soft or firm
 - presence of superficial creases or deep folds examined in sitting and standing positions
2. Assess stoma:
 - location: above, at, or below the line where the abdomen folds when bending
 - lumen (opening) location: above, at, or below the peristomal skin level
 - protrusion: present, absent, or below skin level
 - shape and diameter
 - output type and volume
3. Body and stoma profiles: In addition to the peristomal skin health, the body and stoma profiles should be assessed at every product change. Patients should be instructed on how to accurately assess their peristomal skin at every pouching system change, which can help to identify problems for which patients should seek help from an ostomy nurse. When the ostomy nurse changes a product, he or she should always assess peristomal skin health, preferably with a validated skin assessment tool. Product selection should not be made on the basis of provider preference, a set order of products (ie, start with a flat product and if not successful move to a convex

- Body profile and peristomal skin health should be assessed at every product change whether a stoma nurse is present or not. Patients should be given tools to help them accurately assess their own peristomal skin health and identify when to seek help.
- When an ostomy nurse removes or changes a product, they should always assess peristomal skin health, preferably with a validated skin assessment tool.
- A patient's peristomal body profile should be assessed regularly using a validated body profile assessment tool and should include the following:
 - Consider the shape of the area around the stoma - is it regular, inward or outward?
 - Is the shape around the stoma uniform or variable?
 - Is the area around the stoma soft or firm?
 - Does the skin around the stoma have superficial creases or deep folds?
 - What is the location of the stoma - above bending line, at bending line, below bending line?
 - What is the position of the stoma opening and the height of the stoma?

These 6 steps will help determine the body profile and inform the decision on type of product best suited for that patient (concave, convex or flat). After assessing the patient's peristomal body profile, it will then be up to the clinical judgement of the nurse to determine the best product and accessory combination for that patient. The following should be considered when making that clinical judgement:

 - Patient's health and quality of life goals
 - Output type and volume
 - Patient capabilities
 - Patient support
- Product type recommendations should be based on the patient's body profile and skin assessment, preferably using validated tools. Product type should not be made based on provider preference, a set order of product usage (i.e. start with a flat product and if that doesn't work move to a convex) or through trial and error.
- Contact should be made with stoma patients within 2 weeks of hospital discharge to reassess the patient's body profile and determine which ostomy product type will provide the best security and confidence.
- Contact should be made with patients within 2 weeks after a product change or modification to determine the product's efficacy and action should be immediately taken if security is still an issue.
- Help patients become more proactive in their own health by understanding how to identify changes to their peristomal body profile and when to seek assistance from a Stoma Nurse. Engage and educate patients throughout their journey, provide access to tools and education on how to use the tools and help set realistic goals with patients around optimal health and quality of life.

Figure 3. Consensus-based practice guidelines for the assessment and treatment of persons with an ostomy.

product), or through trial and error. Other methods to aid in assessment include a decision tree for clinicians, a patient self-assessment tool, patient body profile diary, a photo assessment guide, and information gathered from websites that provide evidence-based protocols.

The aforementioned assessments help determine the body and stoma profiles and assist with the decision if a flat, convex or concave, precut or cut to fit skin barrier is best suited for the patient. In addition, that patient's health and quality of life goals, capabilities, and support should be considered when making the clinical judgment. The assessment of the patient's body and stoma profiles, the type and volume of output, and patient-related issues will provide the information to make a decision on the best product and accessory combination for patient security and confidence.

Principles That Guide Patient Care

1. Instruct patients to identify changes in their body and stoma profiles and when to seek assistance from the ostomy nurse. Ostomy nurses need to engage and educate patients by:
 - encouraging them to be proactive in their own health
 - providing access to and education on tools that assess their body and stoma profiles, and peristomal skin health, and know when to seek assistance from an ostomy nurse
 - helping them set realistic goals to reach optimal health and quality of life
2. Maintain frequency of patient contact:
 - within 2 weeks of postoperative hospital discharge following stoma creation or revision to reassess the patient's body and stoma profiles and determine which pouching system will provide the best security (fit) and confidence

- within 2 weeks after a product change or modification to determine product efficacy and what action should be immediately taken if security is still not achieved

Additional Supportive Information

The majority of nurses who responded to the surveys reported that they sometimes or often witness their patients with ostomies using the following coping mechanisms (Figure 4) to manage their lack of confidence in their pouch security by:

- decreasing physical activity
- decreasing physical intimacy
- decreasing socialization
- significantly reducing hobbies and other social activities
- leaving house for short periods of time only
- not staying away from home overnight

Respondents indicated that experiencing leakage was the number 1 reason reported by patients' (Figure 5) withdrawal from physical, leisure, and social activities; 57% observed withdrawal from social and leisure activities after a series of pouch seal leakages or an embarrassing social situation caused by their stoma. A majority, 95% of respondents believed it is part of the ostomy nurse's job to ensure that a person with an ostomy is able to experience an optimal quality of life. However, 13% reported they do not measure quality of life whereas 61% reported assessing quality of life by performing prestoma site markings but after group discussion it was concluded that stoma site marking is not a measure of quality of life. Of the 77% that do assess quality of life, only 24% report using validated quality-of-life instruments and 52% said they do not use a skin or stoma assessment tool.

DISCUSSION

We report findings from a large-scale Modified Delphi Consensus-Building Process project used to identify key factors in assessing body and stoma profiles to determine the best pouching system to reduce and or prevent leakage and peristomal skin complications in persons with an ostomy. This process project resulted in the development of practice guidelines that provide expert guidance on how to assess body and stoma profiles, how to engage and educate patients, and when to follow up with patients after hospital discharge or product change. The overall

goals were to decrease leakage, provide security and confidence, with the long-term objective of improving quality of life.

Consensus among the ostomy nurse respondents indicated that pouch seal security and maintaining peristomal skin integrity are the most important factors in decision-making when determining product choices. This is supported in the literature by multiple authors who report up to 80% of patients with an ostomy develop peristomal skin issues,²⁻⁵ that leakage is a major problem that leads to peristomal skin problems,²³ and results in lack of confidence in living with their stoma.^{22,24} The respondents defined patient assessment guidelines that included the assessment of the peristomal area, stoma, output, patient preferences and abilities, and that these assessment parameters should be used in the selection of the most appropriate pouching system for patient security. It was clear from the results of our survey and data gathered, during the face-to-face panel and expert review group dialogues, that increasing patient quality of life by determining the best pouching system to decrease or prevent pouch seal leakage is the ultimate goal for the person with an ostomy.²⁵ To achieve this goal, pouching system security and optimizing peristomal skin health are paramount.

All ostomy nurse survey respondents recommended that to increase stoma security, peristomal skin health and patient confidence, patients must be educated and actively involved in their stoma care. Engaging patients in assessing their own peristomal, body and stoma profiles at every pouch change, educating them to recognize changes in their peristomal skin health, and encouraging them to contact their ostomy nurse when peristomal changes occur are cornerstones of the guidelines, as they were identified as critically important in effective stoma care. Respondents also identified the need to use validated tools to assess body and stoma profiles, peristomal skin health, and quality of life to ensure patients are fitted with the pouching system that will promote peristomal skin health and provide a high level of security and confidence.

Strengths and Limitations

The strength of the project was the large number and geographical diversity of the respondents, making the results applicable to persons with ostomies worldwide. The Modified

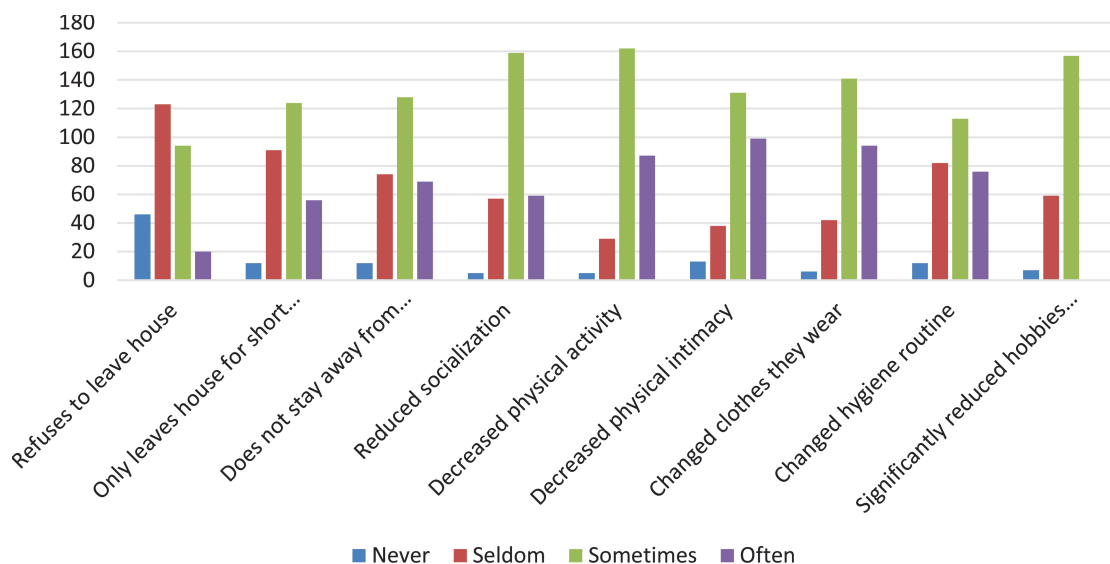


Figure 4. Observed patient coping mechanisms.

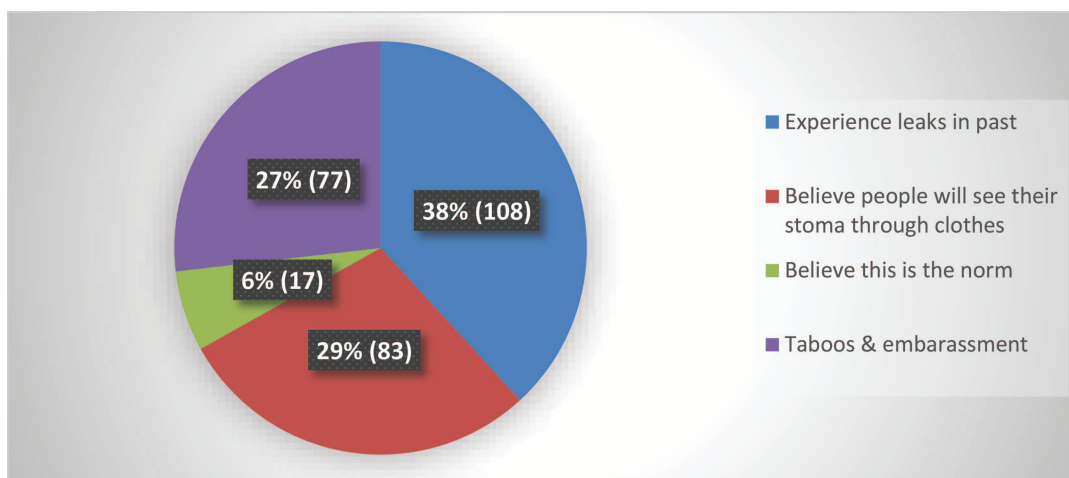


Figure 5. Reasons patients report decreased social, leisure, and physical activities (n = 285).

Delphi Consensus-Building Process, which was developed and led by an International Association of Facilitators, Certified Professional Facilitator, provided an unbiased approach to develop the surveys, administer them, and analyze results. Another strength was the depth and experience of the expert panel and the expert review group, all of whom were highly skilled ostomy nurses involved throughout the entire project processes. There was wide representation from many countries and languages, including Spanish-speaking nurses at the Ostomy Days Dialogue. A limitation was the inability to send the survey to China (China lacks the email platform to participate in an email survey), but ostomy nurses from China did participate in the Ostomy Days ratification process. Another limitation of the study was that the consensus was only obtained from more developed countries such as North America, Europe, and Australia. Finally, industry sponsorship could lead participants to bias toward Coloplast products; however, all survey questions and the resulting practice guidelines focused on type of pouching system (flat, convex, and concave) not brand, decreasing bias as a factor in the study.

CONCLUSIONS

We describe the process for, and outcomes of, the development and dissemination of consensus guidelines that provide guidance for nurses providing ostomy care. Lack of a secure pouch seal leads to peristomal skin problems and is one of the major reasons that persons with ostomies experience a lack of confidence in managing their ostomies. Ostomy nurses should ensure persons with ostomies experience as few pouch seal failures as possible, by providing their patients with the best fitting pouching system, in order to promote peristomal skin health and help the patient develop and maintain confidence in managing their ostomies. Assessing the patient's peristomal body and stoma profiles and utilizing the product type best suited to provide ultimate security and comfort is critical. Engaging and educating patients and families in proactively assessing body and stoma profiles and peristomal skin health at every product change is important to ensure early detection of peristomal changes and pouching seal problems and to insure patient confidence in living with their stoma. We propose that this work serve as a tool for ostomy nurses to provide guidance on choosing the best pouching system using these consensus guidelines.

KEY POINTS

- ▶ A consensus document was developed that identified key factors in assessing body and stoma profiles to determine the best pouching system to reduce and/or prevent leakage and peristomal skin complications.
- ▶ Pouch seal security and maintaining peristomal skin integrity are the most important factors in decision-making when determining the selection of a pouching system.
- ▶ Body and stoma profiles and the patient's health, quality-of-life goals, capabilities, and help managing the stoma (if needed) should always be assessed when choosing an ostomy product.
- ▶ The most common reasons for a product change are pouch seal leakage and peristomal skin complications.

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