

# Clinical preventive-based best practices to reduce the risk of peristomal skin complications – an international consensus report

## ABSTRACT

Evidence indicates that peristomal skin complications (PSC) are a common problem for people with an ostomy and have serious implications on their overall health and quality of life. While there is evidence and documentation on the cause and effect of PSC, there is little written on the risk factors or on how to maintain peristomal skin integrity and prevent PSC. To address this gap, a panel of ostomy experts was convened to conduct a process to reach an international consensus on PSC risk factors. A large-scale modified Delphi consensus-building process was conducted between September 2019 and October 2020. A total of 4,285 online survey responses were received from 36 countries across six continents. The result was a consensus focused on the prevention of PSC and on the individual patient risk factors healthcare providers should consider when determining the best pouching system and care plan for ostomy patients. The consensus supported the development of a PSC risk factor model. The model was subsequently ratified in October 2020. The purpose of the model is to help guide healthcare providers in assessing the risk factors for developing a PSC for each patient and ultimately guide healthcare providers to prevent skin damage, maintain healthy peristomal skin, and support the overall health, wellbeing and quality of life of ostomy patients.

**Keywords** leakage, moisture-associated skin damage, patient quality of life, peristomal skin complications, risk factors

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## INTRODUCTION

It is reported that over 700,000 people are living with a stoma in Europe<sup>1</sup>, over 1 million in the United States<sup>2</sup> and close to 1 million in China<sup>3</sup>. The literature suggests that up to 80%

of stoma patients experience peristomal skin complications (PSC)<sup>4-8</sup>. PSC negatively affect the quality of life of people with an ostomy<sup>9-11</sup>. Claessens et al<sup>12</sup> reported that 91% of people with an ostomy surveyed said they worry about leakage,

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40% said they wake up at night because of their ostomy, 33% said that they limit their physical and social activities and 12% indicated that they socially isolate. However, while the literature supports a direct correlation between quality of life and PSC, understanding the risks to peristomal skin health are not well documented<sup>13</sup>.

The peristomal skin, the skin area in circumference around the stoma, plays an important role in the effective functioning of the ostomy pouching system. The peristomal skin provides the surface that the pouching system adheres to, and therefore healthy peristomal skin plays a critical role in the effective functioning of the pouching system<sup>14</sup>. The main role of the pouching system is to collect effluent that is diverted through the patient's stoma. Effluent typically contains faecal matter, urine and mucous which is corrosive and can cause damage to skin within a short period of time<sup>15-18</sup>. This damage is often referred to as irritant contact dermatitis in the peristomal area or peristomal contact dermatitis<sup>19</sup>. Peristomal contact dermatitis can present as erosion of the peristomal skin, red, painful, itchy skin, rash, inflammation and infection. The most effective way to prevent irritant contact dermatitis is to ensure a consistent secure seal, thus preventing leakage of stoma output onto the surrounding skin<sup>20,21</sup>.

PSC are well documented as the most prevalent complication faced by people with an ostomy and the most common reason people with an ostomy seek outpatient care and specialised ostomy nursing services<sup>22</sup>. However, there is minimal evidence in the literature to help healthcare professionals to engage in early identification of the risk factors for ostomy patients in developing PSC<sup>13</sup>. This project was designed to reach consensus among both clinical experts in ostomy care and nurses and practitioners around the world working with ostomy patients regarding risk factors that may cause PSC. The purpose of reaching consensus on risk factors for PSC is to

support prevention-based decision-making in ostomy care and improve peristomal skin care practices. This article will describe the process used to reach consensus on the risk factors and the results agreed to by the experts in the study.

## METHODS

Consensus building is the process of helping groups reach a common understanding on an issue or solution<sup>23</sup>. The concept of consensus building is based on the belief that when people think together, they can make better decisions<sup>24,25</sup>. This consensus process was informed by a systematic review of the literature on PSC risk factors and a series of consensus dialogues involving over 400 stoma nurses from across Europe and North America. This methodology ensured the model was based on literature evidence, provided by the literature review and on experiential evidence, provided through dialogues with over 400 stoma nurses and from the survey results from the modified Delphi process (Figure 1).

An expert panel of 15 dermatologists and ostomy care nurse specialists from eight countries provided stewardship for the project: Birgitte Dissing Andersen (Denmark); Janice Colwell (USA); Gill Down (UK); Tracy Virgin-Elliston (UK); Jane Fellow (USA); Louise Forest-Lalande (Canada); Gregor Jemec (Denmark); Tonny Karlsmark (Denmark); Doris Kost (Germany); Lina Martins (Canada); Svatava Nováková (Czech Republic); Rosalind Probert (Australia); Oirda Samai (France); Emilie Trividic (France); Chantal Tielemans (Belgium). Coloplast A/S funded the project. A modified Delphi process was utilised to help develop the consensus which led to ratification of the model and included elements of Delphi survey methodology, nominal group techniques (NGT-R) and process facilitation<sup>26-28</sup>.

Two surveys were sent out to ostomy healthcare providers around the world. The first survey was sent out November

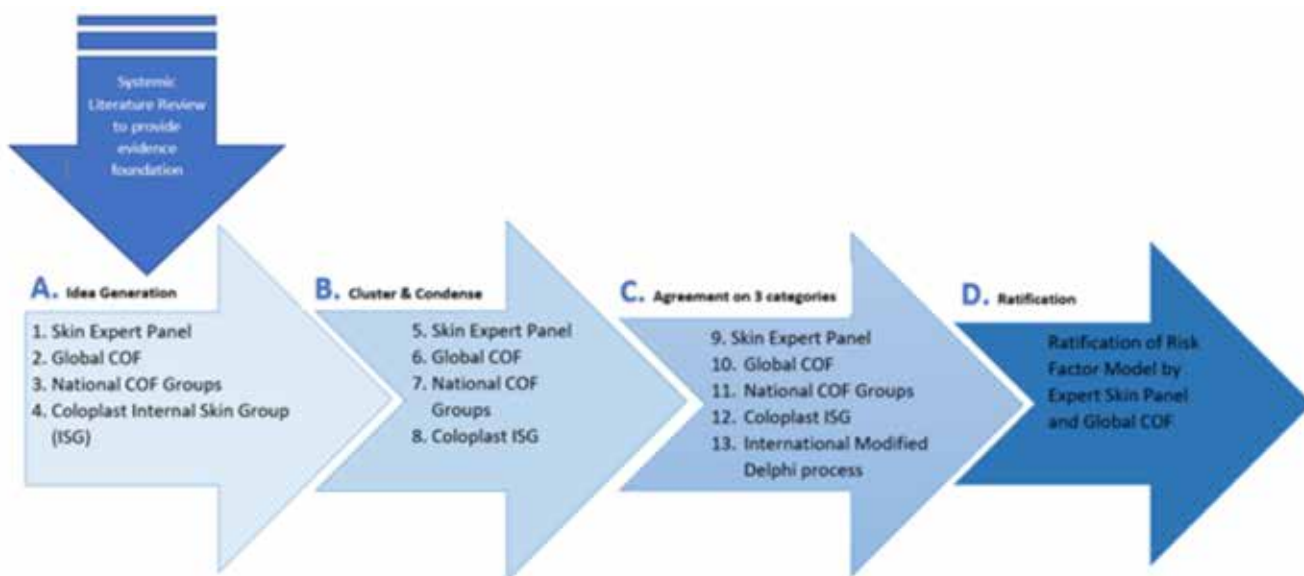


Figure 1. Method for development of the risk factor model, using both literature evidence and experiential evidence.

A. Idea generation and risk factor identification. B. Condensation of risk factors into 10 overall categories. C. Condensation of risk factors into three categories and international modified Delphi process. D. Ratification of the model. COF: Coloplast Ostomy Forum & Expert Panel

2019 and remained open for 30 days. The survey invitation was emailed to healthcare professionals in 17 different languages, across 36 countries, spanning six continents, through industry and professional association mailing lists. The survey was anonymous and was conducted virtually. A total of 2262 responses were received. The first survey was designed to identify current practices, tools and methodologies, and to explore respondents' views on risk factors for PSC, as well as identify the strategies used to prevent and treat PSC. The results of the survey were analysed by the expert panel and assessed against the literature review findings.

The second survey opened in late January 2020. Survey invitations were emailed to the same invitees as the first survey, this time in 16 languages (the second survey was not sent out in Italian as Italy was under lockdown due to COVID-19 at the time) and across 35 countries. The second survey was designed to confirm the risk factors identified in the first survey and the literature findings, the results of which were again reviewed by the expert panel. Due to the COVID-19 global pandemic, the second survey remained open for 90 days, in recognition that healthcare professionals' time was focused on pandemic response not responding to research surveys. A total of 2023 responses were received within the 90 days and again the results were analysed and discussed at the expert panel.

The data collected from surveys 1 and 2 were used to develop a third survey which was sent to the expert panel (n=15). The expert panel members ratified the list of risk factors based on the results of the literature review, the two global surveys, and in person (September 2019) and virtually (throughout 2020) facilitated dialogues.

### Participants

The first survey was responded to by 2262 healthcare professionals. The response breakdown by region can be seen in Figure 2. The majority, 79%, of respondents were specialised

ostomy nurses, 15% were ward or outpatient nurses, 4% were home care/community health workers; the remaining 2% included physicians, surgeons, dermatologists and healthcare managers. A total of 74% of respondents reported they had more than 10 years' experience as a healthcare professional.

The second survey received 2023 responses and received more responses from Asia than survey 1, but less from the Middle East and Africa. The expert panel concluded this shift was due to the heavy work/time burden of the pandemic on healthcare professionals in specific regions, vis-à-vis the timing of the survey.

### Ethical considerations

The project received approval from the Biomedical Research Alliance of New York LLC Organizational Review Board (Study Specific #20180925) without qualifiers. All three surveys were anonymous. Demographic information gathered focused on country of residence, clinical credentials, type of clinical practice, and years of experience. No identifiable personal information was collected. Coloplast A/S funded the study, however, the research questions, project oversight and resulting consensus were the responsibility of the expert panel. Coloplast A/S products were not mentioned in the surveys nor in communication with participants. The resulting PSC risk factor model does not reference or recommend any products and focuses solely on the identification of risk factors for preventing PSC.

### Data management and analysis

Survey data was comprised of a total of 4285 anonymous survey responses and was analysed using descriptive statistics utilising Excel Pivot Tables (Excel 365 v 2109). All data was analysed and reported in aggregate and by basic demographic data – type of respondent (nurse, physician, etc) and location of practice (region or country). Data were analysed using descriptive statistics using mean, median, mode and standard

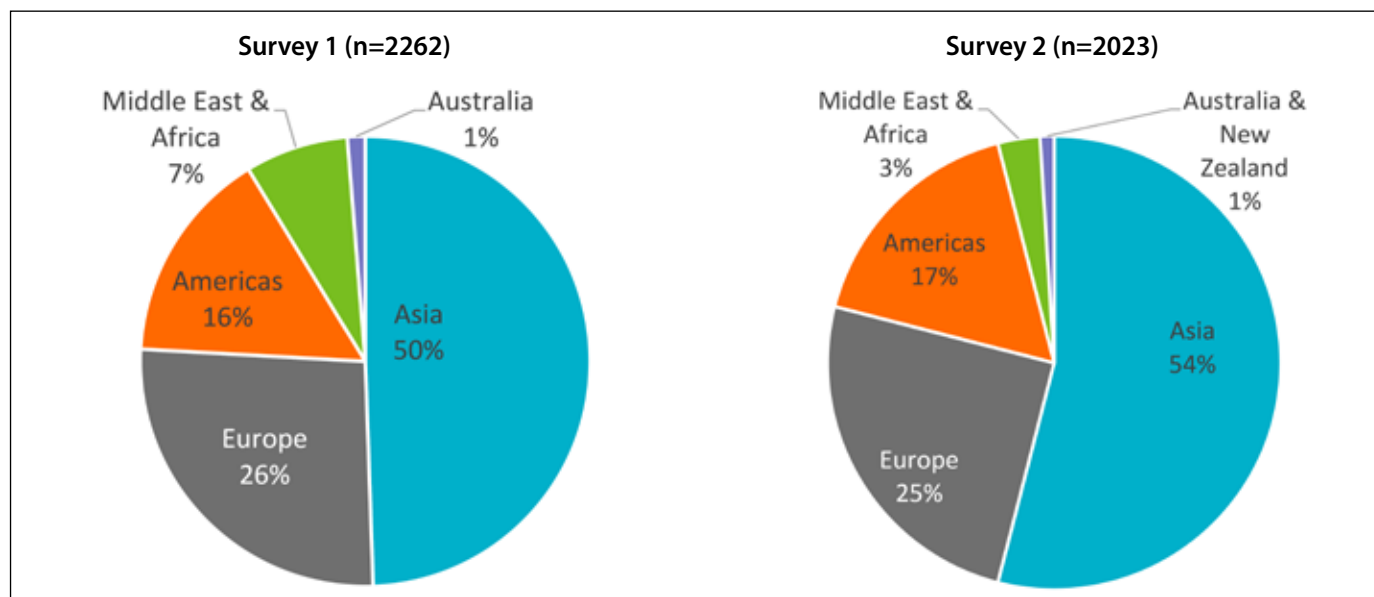


Figure 2. Survey responses by geographic region

deviation, as well as comparative analysis between regions and between professional groups. Significance was defined as  $p < 0.050$ .

## RESULTS

The results clearly indicate that survey respondents believe it is important to maintain peristomal skin integrity for positive patient outcomes. A total of 93% of respondents agreed that peristomal skin health is very important to patient overall health and wellbeing; 99% of respondents agreed that preventing PSC should be the aim of healthcare providers and 97% agreed that PSC risk factors should *always* be considered when determining the most effective pouching system for a patient. However, when asked to estimate the percentage of their patients who experienced PSC in the last 6 months, the average response was 42%, with a standard deviation of  $\pm 22.47\%$  (Table 1). The high degree of variability in responses ( $\pm 22.47\%$ ) was consistent across all regions (Table 2). There were no significant statistical differences between responses from experienced healthcare professionals and respondents with less than 5 years of healthcare experience. The results indicate that neither geography nor experience of the healthcare provider impacts the probability of a patient experiencing PSC.

When asked about peristomal skin health, 85% of respondents agreed that it is a realistic goal for peristomal skin to look and feel exactly like skin outside the peristomal area, with 11% neither agreeing nor disagreeing and only 4% disagreeing. However, only 47% ( $n=883$ ) of respondents reported consistently using a peristomal skin assessment tool in their practice. Of the tools identified, the most frequently used tool was the ostomy skin tool that uses DET scores (Table 3)<sup>29</sup>.

The main health indicators observed in patients with PSC were identified, in descending order, as (Figure 3):

1. Moisture-associated skin damage (MASD).
2. Contact dermatitis.
3. Mucocutaneous separation.
4. Bacterial, fungal or yeast infections.
5. Skin stripping.

Table 1. Percentage of their ostomy patients that experienced PSC in the last 6 months, as reported by survey respondents

Experience of PSC	n (%)
Total number of respondents	1,856
Median percentage response	40.00%
Mean percentage response	42.27%
Standard deviation	24.77%
No. respondents that said that, in past 6 months:	
0% of their patients had experienced PSC	26 (1.4)
100% of their patients had experienced PSC	18 (0.96)
20% or less of their patients had experienced PSC	432 (23.28)
80% or more of their patients had experienced PSC	169 (9.1)

6. Medical adhesive-related skin injuries (MARS).
7. Suture granulomas.
8. Hyperplasia/tissue overgrowth.
9. Folliculitis.

The main effects of PSC on patients' quality of life were: increased worry about leakage, identified by 90% of respondents; decreased social activities/social isolation, identified by 88% of respondents; decreased confidence in the pouching system by patients, identified by 82% of respondents; increased pain and itching, also identified by 82% of respondents; decreased feelings of security and confidence, identified by 77% of respondents; negative affect on sleep patterns, identified by 76% of respondents; and decreased productivity of patient, identified by 60% of respondents.

Table 2. Percentage of patients who experienced PSC in the last 6 months by region

Region	Percentage of respondents whose patients experienced PSC in last 6 months	Median response	Standard deviation
Americas	50%	50%	$\pm 26.38\%$
Asia	39%	35%	$\pm 24.79\%$
Europe	42%	42%	$\pm 22.65\%$
Middle East & Africa	41%	40%	$\pm 24.60\%$

Table 3. Most commonly used peristomal skin assessment tool

Most commonly used peristomal skin assessment tool	Percentage answered	No. responses (n=883)
Ostomy Skin Tool (DET score & AIM Guide)	69.31%	612
SACS Tool (evaluating peristomal skin)	31.26%	276
IADS Instrument (Incontinence-Associated Dermatitis and its Severity)	19.82%	175
The CLASI Instrument (Cutaneous Lupus Erythematosus Disease Area and Severity Index)	17.33%	153
SCORAD Index (Severity Scoring of Atopic Dermatitis)	6.68%	59
STAR – a consensus for skin tear classification	4.30%	38
PASI (Psoriasis Area Severity Index)	3.74%	33
PSAG (Peristomal Skin Assessment Guide)	2.27%	20
Other (please specify)*	11.66%	103

\* Other tools identified were primarily institutionally specific tools

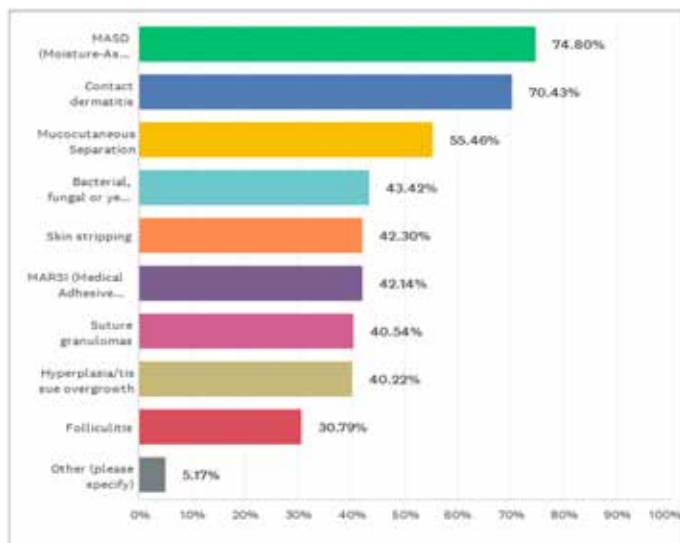


Figure 3. What have you observed are the main health indications of PSC in your patients? (answered by 1877 survey respondents)

The most often identified risks, for patients developing PSC, are presented below in descending order, starting with those factors most often identified by respondents (Table 4):

1. Ostomy construction.
2. Type of ostomy.
3. Stoma management/self care techniques.
4. Body profile/BMI.
5. Limited patient self-care training and education.
6. Physical capacity (vision, dexterity, flexibility, mobility).
7. Pre-existing skin conditions (allergies, psoriasis, etc).
8. Compliance with care regime.
9. Co-morbidities and underlying diseases (i.e., Crohn's disease).
10. Limited access to stoma care nurses/specialists.
11. Lack of family/care/social network.
12. Age.
13. Limited allowance of ostomy products within the healthcare system.
14. Standard of living.
15. Mental capacity.
16. Limited types of ostomy product availability.

Respondents identified the following as the most common reasons patients develop PSC (Figure 4):

- Leakage of stoma effluent (poor pouching seal).
- Scars, creases and folds in the peristomal skin.
- Ostomy construction/height & location.
- Not dealing with minor skin irritations in a timely fashion, allowing the condition to worsen.
- Patient compliance with care regime, including proper cleaning of peristomal skin.

When asked to identify the main prevention strategies they currently use to maintain optimal peristomal skin health, respondents indicated choosing a pouching system based on the patient's body profile and patient education as the top two strategies (Table 5).

Respondents were also asked about their healthcare systems. To determine the effects of delivery and affordability of care, respondents were asked how often the issue of cost influences decision-making when determining the best pouching system for patients. The responses varied across regions but not across system types (i.e., public- vs private-based systems). Respondents from Asia, USA and Canada tend to take costs into consideration more often, while respondents from Europe, the Middle East and Africa do not consider costs as often (Figure 5). When asked about post-discharge programs for people who go through stoma surgery, overall, only 56% of respondents indicated that all of their ostomy patients have access to post-discharge programs, with the Americas being the lowest at 43% and Europe being highest at 72%. The length of post-discharge programs also varied greatly across regions, with Europe being the longest, 51% reporting their post-discharge

Table 4. Main risk factors identified by respondents for developing PSC

Risk factor	Percentage answered	No. responses (n=1631)
Ostomy construction	58.06%	947
Type of ostomy	57.20%	933
Stoma management/self care techniques	56.84%	927
Body profile or BMI	42.24%	689
Limited patient self-care training and education	36.48%	595
Physical capacity (vision, dexterity, flexibility, mobility)	32.25%	526
Pre-existing skin conditions (allergies, psoriasis, etc)	30.72%	501
Compliance with care regime	29.49%	481
Co-morbidities and underlying diseases (i.e. Crohn's disease)	27.47%	448
Limited access to stoma care nurses/specialists	23.73%	387
Lack of family/care/social network	19.44%	317
Age	17.90%	292
Limited allowance of ostomy products within the healthcare system	13.92%	227
Standard of living	13.30%	217
Mental capacity	11.10%	181
Limited types of ostomy product availability	9.38%	153
Skipped	38.68%	631



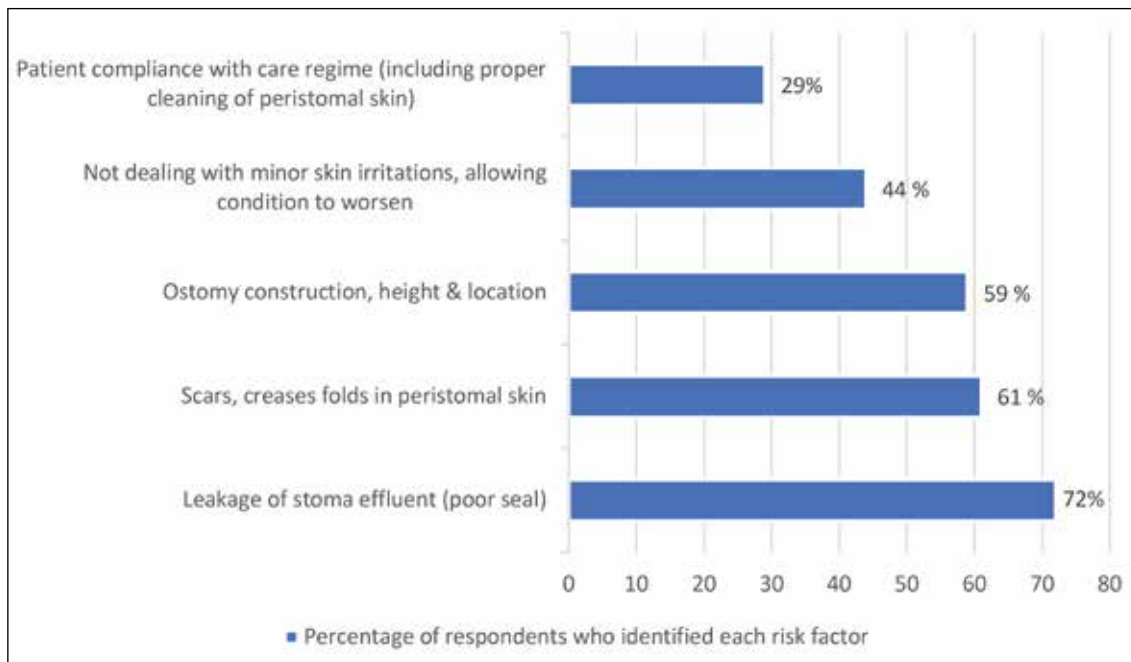


Figure 4. Five most common risk factors leading to PSC in respondents' patient population

programs are longer than 12 months; in the Americas, 55% reported their post-discharge programs are 2 months or less.

The survey results also offer insights on respondents' experience regarding ostomy pouching systems. A total of 97% of respondents indicated that it is important or very important to have a range of products available to meet individual ostomate needs and enable adaption to each individual patient's body profile. Overall, 99% of respondents indicated that product considerations were important in assessing a patient's risk of developing PSC. Finally, respondents identified those considerations seen as most important regarding the adhesive properties of products in the prevention of PSC, in order of prevalence:

1. The ease of application and removal.
2. The ability to follow body movements.
3. The erosion resistance of adhesive.
4. The need to add accessories to aid in the product effectiveness.
5. The potential for skin stripping.
6. The speed with which the product attaches to the skin (immediate adherence to the skin).

Table 6 indicates the factors that respondents identified as necessary to determine the optimal pouching system for patients. Three risk factor categories were supported by the survey respondents: the patient (body profile, physical and mental capabilities and social supports); ostomy products (availability, wear time, adhesive properties, adaptability, etc); and the healthcare system (costs, availability of healthcare providers and specialists, guidelines and limitations, insurance provisions, etc) (Table 7).

## DISCUSSION

The survey results show there is strong clinician support for prevention of PSC among respondents. Reacting once peristomal skin issues arise is difficult because once the

Table 5. Main prevention strategies respondents reported using to maintain optimal peristomal skin health

Answer choices	Percentage answered	No. responses (n=1631)
Choosing a pouching system/ostomy product based on the patient's body profile	84.73%	1382
Educating patients in correct application of pouching system	83.69%	1365
Educating patients on proper cleansing protocols	68.00%	1109
Educating patients in the correct adaptation of the chosen pouching system	65.67%	1071
Use of rings	56.71%	925
Use of powders	52.73%	860
Use of protective films	52.30%	853
Early intervention and referral	51.38%	838
Use of pastes	46.05%	751
Change in wear time	45.74%	746
Use of adhesive removal solutions	44.76%	730
Use of creams	15.02%	245
Other (please specify)	3.31%	54

peristomal skin is compromised, a secure seal is harder to obtain, resulting in leakage and further deterioration of the peristomal skin<sup>5,8,21</sup>. When skin integrity around the stoma site is compromised, appliance adherence problems are compounded; therefore, preventing PSC is paramount<sup>14,19,22</sup>.

Respondents agreed that peristomal skin health is important to people with an ostomy's overall health, wellbeing and quality of life and that it is a realistic goal for peristomal skin to look and feel like the skin outside of the peristomal area<sup>30</sup>. To maintain healthy peristomal skin for the life of the person with an ostomy, healthcare providers should identify the risk factors for developing PSC of each patient periodically throughout the patient journey<sup>22,29</sup>. Identifying the risks will allow healthcare providers, in partnership with patients, to choose the appropriate pouching system and develop the best care plan to mitigate the identified risks and maintain/promote peristomal skin health<sup>20</sup>.

The Modified Delphi Process resulted in a strong consensus around the importance of maintaining peristomal integrity and the risk factors that must be considered in the prevention of PSC. The evidence identified in the literature review<sup>13</sup> and the experiential evidence gathered through the surveys and the facilitated dialogues led to the development and ratification of the PSC risk factor model (Figure 6).

The model categorises peristomal risk factors into three categories – the individual with a stoma, the ostomy product solutions, and the healthcare system in which the patient lives. Each of these categories encompass a list of risk factors that should be considered by healthcare providers when assessing a patient's risk of developing PSC. The PSC risk factor model was designed to guide healthcare providers in identifying the risks for each patient so that an individualised care plan

Table 6. Factor respondents always consider when determining the best pouching system for patients

Factor in determining optimal pouching system	% of respondents who reported always considering this factor
Stoma construction – height, diameter, location	90%
Patient's peristomal body profile	85%
Ability to adapt product to body shape and follow body movement	83%
Pre-existing skin conditions/skin damage	81%
Patients' ability to follow care plan	78%
Activity level of patient	75%
Adhesive properties of appliance	74%
Pressure from convex/coupling, rings, belts, etc	66%
Risk of skin stripping from too frequent removal of adhesives	61%
Cost of products, insurance limitations, ability to pay, etc	59%
Ballooning/pancaking	48%

can be developed to support the peristomal skin health and overall wellbeing of the ostomate. The international nature of the survey results supports the model as a global framework that can provide an evidence-based foundation for regional decision-making on preventing PSC.

### Strengths and limitations

The strength of this project stems from the large number and geographic diversity of the participants. Close to 4,300

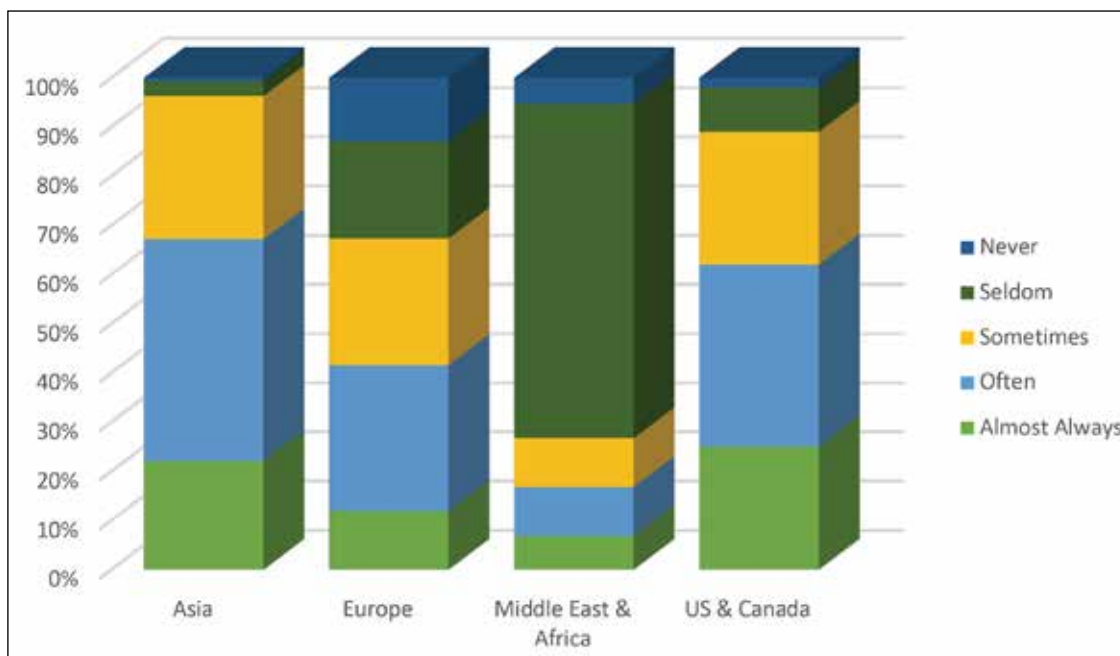


Figure 5. How often the issue of costs influences decision-making when determining the best pouching system for patients, reported by region

survey responses were received from experienced ostomy care providers spread across six continents. The multinational, multicultural and multilingual nature of the study makes the model uniquely positioned to allow for regionally appropriate emphasis and implementation variations based on system requirements and patient expectations.

Another strength was the depth and breadth of experience of the expert panel members who acted as stewards for the process. The skin expert panel consisted of highly experienced ostomy nurses and dermatologists who have impressive research resumes and are highly regarded in the field.

A limitation of the study was the inability, due to the anonymity of survey respondents, to know how many of the respondents who responded to the first survey also responded to the second survey. Therefore, the authors are unable to calculate a definitive number of overall participants. Finally, industry sponsorship of this study could lead respondents to bias towards Coloplast A/S products; however, no survey questions, nor any of the communication with respondents, included product names, types or descriptions. Survey respondents were not in any way compensated or incentivised to respond to the

surveys. Additionally, respondents were anonymous to both the research team and industry sponsorship partner. It is the opinion of the authors that this decreased bias in the survey results.

## CONCLUSION

Peristomal skin integrity is necessary to obtain a secure seal for an ostomy pouching system. If the ostomy pouching system is not secure, effluent can leak onto the peristomal skin, causing PSC such as skin damage and erosion. Preventing leakage and PSC is paramount to an ostomate's health and quality of life. This study was designed to identify the risk factors in preventing PSC. The risk factors were categorised under three headings: the individual with a stoma (body profile, capabilities, social situation); the healthcare system (standard of care, access and education); and ostomy products (usage and technical properties). An international consensus was reached on the risk factor model and its importance in focusing on prevention of PSC. Agreement was also achieved in that the goal for all healthcare providers should be to maintain peristomal skin to the same condition/health of skin outside the peristomal area. The resulting PSC risk factor model was

Table 7. Support for risk factor categories, asked in survey 2 (n=2023)

Category	Extremely important	Very important	Somewhat important	Slightly important	Not important
The patient – body profile, physical and mental capabilities, social supports	44%	48%	7%	0.35%	0.25%
Ostomy products – availability, adhesive properties, wear time, adaptability, etc	46%	44%	9%	0.5%	0.2%
The healthcare system – availability of providers and specialists, insurance, costs, national/ regional policies and guidelines, etc	42%	42%	13%	2%	0.4%

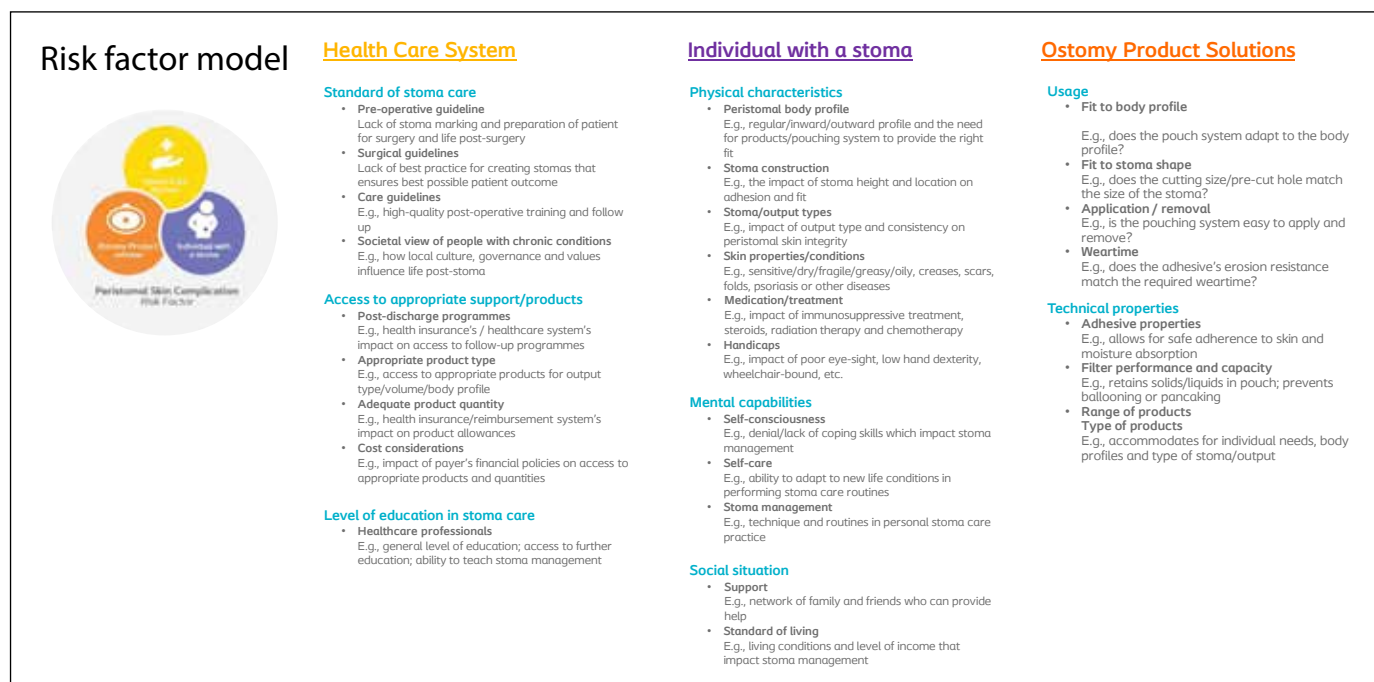


Figure 6. PSC risk factor model<sup>13</sup>



unanimously ratified by the expert panel, and they, along with the research authors, advocate its use by healthcare providers as a first line of defence to identify risks and guard against PSC.

## CONFLICT OF INTEREST

The project was supported by Coloplast A/S. G Down, B Andersen, L Martins, T Karlsmark and G Jemec are all members of the Coloplast Skin Expert Panel. K Bain has conducted facilitation contracts for Coloplast A/S in the past. M Bain has provided data analysis services for Coloplast A/S in the past. A Steen Hansen, L Feldskov and C Bechshoeft all work for Coloplast A/S.

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