# **OSTOMY CARE**



# A Cost-Utility Model of Care for Peristomal Skin Complications

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OPEN

# ABSTRACT

**PURPOSE:** The aim of this study was to evaluate the economic and humanistic implications of using ostomy components to prevent subsequent peristomal skin complications (PSCs) in individuals who experience an initial, leakage-related PSC event.

**DESIGN:** Cost-utility analysis.

**METHODS**: We developed a simple decision model to consider, from a payer's perspective, PSCs managed with and without the use of ostomy components over 1 year. The model evaluated the extent to which outcomes associated with the use of ostomy components (PSC events avoided; quality-adjusted life days gained) offset the costs associated with their use.

**RESULTS:** Our base case analysis of 1000 hypothetical individuals over 1 year assumes that using ostomy components following a first PSC reduces recurrent events versus PSC management without components. In this analysis, component acquisition costs were largely offset by lower resource use for ostomy supplies (barriers; pouches) and lower clinical utilization to manage PSCs. The overall annual average resource use for individuals using components was about 6.3% (\$139) higher versus individuals not using components. Each PSC event avoided yielded, on average, 8 additional quality-adjusted life days over 1 year.

**CONCLUSIONS:** In our analysis, (1) acquisition costs for ostomy components were offset in whole or in part by the use of fewer ostomy supplies to manage PSCs and (2) use of ostomy components to prevent PSCs produced better outcomes (fewer repeat PSC events; more health-related quality-adjusted life days) over 1 year compared to not using components.

**KEY WORDS:** Economics, Ostomy, Peristomal skin complications, Quality of life

# Glossary

*Cost-utility analysis*: One of a family of analytic techniques used for economic evaluation in healthcare; costutility analysis is designed to compare the value (costs and outcomes) of alternative interventions or treatment strategies, including any differences in individuals' perceived state of health or well-being.

*Disutility*: A decrease in an individual's perceived state of health or well-being.

*One-way sensitivity analysis*: Allows a reader to understand how changes in any one parameter will impact the results generated by an analysis.

*Quality-adjusted life day (QALD)*: A preference-based measure of health in terms of individuals' self-perception of their health and well-being; QALD is measured on an interval scale ranging from 0 (1 day in worst health state possible) to 1 (1 day in the best health state possible). Each health state in between is assigned a preference weight, or utility, ranging from 0.0 to 1.0. Use of QALD allows decision makers to compare the value of interventions in terms of the full range of outcomes that are important to patients.

# Introduction

More than 1 million people in North America live with a permanent ostomy, and some 100,000 new ostomy surgeries are being performed each year in response to a variety of conditions, including cancer and certain gastrointestinal diseases.<sup>1,2</sup> Ostomy or stoma surgery brings a portion

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of the gastrointestinal or urinary tract to the abdominal surface. An ostomy barrier attaches to the skin around the mucocutaneous junction, where the skin meets the stoma. A pouch attached to the barrier collects the effluent, either urine or feces. A barrier that is not secure against the peristomal skin will leak effluent, which can cause skin damage; thus, a secure seal is crucial.<sup>3</sup>

A secure seal of the ostomy barrier against the skin can be difficult to obtain, especially as the stoma and surrounding skin evolve as edema resolves during the immediate postoperative period; when the stoma is located in a challenging anatomical position; when the peristomal skin is uneven because of scars or skin folds; or when the peristomal skin is fragile owing to age or cutaneous conditions. In these cases, component products (currently classified as ostomy accessories) such as skin barrier rings or seals, stoma paste, or barrier strips can be used to fill in and eliminate gaps, thereby creating a secure seal between the ostomy barrier and the peristomal skin.<sup>4</sup> Other components, such as adhesive removers/releasers, also may be used to support integrity of the barrier seal. Appropriate use of these components allows conventional ostomy barriers to better conform to challenging abdominal planes, thereby preventing leakage, protecting peristomal skin, and preventing the occurrence/recurrence of peristomal skin complications (PSCs).

The epidemiology of PSCs has not been adequately studied in the published literature. Reports of the incidence and prevalence of PSCs vary greatly.3,5 Study findings are difficult to compare due to differences in study population, study design, ostomy site, ostomy type, time since surgery, operational definitions of PSC, PSC assessment, and response rate.5 Nevertheless, there is widespread agreement that (1) PSCs are common and have a significant detrimental impact on health-related quality of life<sup>6,7</sup>; (2) unattended, a mild PSC can progress into a more severe condition<sup>3</sup>; (3) peristomal leakage (effluent on the skin) is a key causative factor for PSCs<sup>8,9</sup>; (4) besides discomfort and pain, damaged peristomal skin can reduce adhesion of the ostomy barrier, which, in turn, increases the risk of leakage and the necessity for frequent pouching system changes<sup>10,11</sup>; (5) the development of a PSC often necessitates greater than usual use of ostomy supplies9; and (6) addressing PSCs at an early stage is essential in order to avoid long-term, debilitating, and expensive complications.12

The results of a recent investigation estimating the costs associated with different forms of PSC suggest that prompt management of leakage is cost-effective and exerts a positive impact on daily health-related quality of life for individuals living with an ostomy.<sup>12</sup> In addition, clinical experience emphasizes the role of ostomy components in preventing the occurrence of common stoma-related problems.<sup>6,13</sup> The aim of this study was to evaluate the economic and humanistic implications of using ostomy com-

ponents to prevent subsequent PSCs in individuals who experience an initial, leakage-related PSC event.

### Methods

We developed a 1 year cost-utility model to simulate a cohort of 1000 individuals living with an ostomy. The model compares the 1-year outcomes (PSC events avoided; quality-adjusted life days gained) and costs (barriers/ pouches; ostomy components; clinical utilization) associated with 2 scenarios: (1) a skin Barrier Alone scenario assumes that ostomy components are not available to manage PSCs, and (2) a skin Barrier and Components scenario assumes that ostomy components are used selectively, with clinical oversight, to individualize barrier fit/ adhesion. Proper barrier fit and adhesion are hypothesized to prevent PSCs among individuals who have a first PSC event. The perspective is that of a payer or health system. Costs are estimated in 2014 Canadian dollars.

#### **Model Inputs**

Baseline inputs for the model are drawn from published sources where available (eg, articles identified in a MEDLINE search using key words such as "ostomy/ economics" and "surgical stomas/adverse effects"; manufacturer-suggested retail price lists), as indicated. Where published estimates were nonspecific or unavailable, we asked a panel of 26 enterostomal therapy (ET)/WOC nurses in 2 North American advisory board meetings to offer "clinically reasonable" values based on informal (nonrandomized) chart review and/or their clinical experience. The nurses in our panel had an average of 11 years of clinical ostomy experience; 2 (A.M., A.T.) are authors. All inputs were subsequently varied over a range of values to assess the robustness of modeled results.

Our model is constructed around twelve 30-day cycles. At its outset, the model assumes hypothetically that all individuals have established a stable pattern for use of either a 1-piece or a 2-piece barrier/pouch system (Table 1) and have not experienced leakage-related PSCs.

This stable pattern of ostomy supply use may be interrupted in any cycle by PSCs, which are assumed to occur at an annual rate of 65% (5.4% per month). In the model, a PSC may be mild (25%), moderate (55%), or severe (20%) (Table 2). These incidence and severity estimates are congruent with published literature<sup>5</sup> and affirmed by our panel of practicing ET/WOC nurses. To simplify the analysis, we assume conservatively that PSC events occur at the start of a 30-day cycle and are resolved within the same cycle.

In both scenarios (Barrier Alone; Barrier & Components), our baseline analysis assumes that individuals experiencing PSCs will attempt to self-manage these events by increasing their usual frequency of barrier changes in an effort to minimize exposure to the irritating

| Ostomy System              | % Of Cohort | Component | Unit Cost <sup>a</sup> | Change Frequency |
|----------------------------|-------------|-----------|------------------------|------------------|
| One-piece closed           | 6           | System    | \$4.87                 | 2 times per day  |
| One-piece drainable convex | 26          | System    | \$16.70                | 2 times per week |
| One-piece drainable flat   | 6           | System    | \$9.15                 | 2 times per week |
| One-piece urostomy convex  | 8           | System    | \$14.50                | 2 times per week |
| Two-piece closed convex    | 6           | Barrier   | \$13.30                | 2 times per week |
|                            |             | Pouch     | \$3.03                 | 2 times per day  |
| Two-piece closed flat      | 6           | Barrier   | \$8.80                 | 2 times per week |
|                            |             | Pouch     | \$3.03                 | 2 times per day  |
| Two-piece drainable convex | 25          | Barrier   | \$12.70                | 2 times per week |
|                            |             | Pouch     | \$6.50                 | 2 times per week |
| Two-piece drainable flat   | 18          | Barrier   | \$8.80                 | 2 times per week |
|                            |             | Pouch     | \$6.50                 | 2 times per week |

<sup>a</sup>Manufacturer's Suggested Retail Price, British Columbia, 2014 Canadian dollars.

effluent. In some cases, more frequent pouching system changes are successful and the PSC resolves without further intervention. In other cases, individuals will seek the advice of an ET/WOC nurse (Table 2). For example, in the absence of ostomy components (Barrier Alone scenario), we assume that individuals experiencing a mild PSC will, in an effort to get leaking under control, increase their barrier change frequency from twice-weekly to everyother-day (3.5 barrier changes per week), which represents 175% of (75% increase over) their usual use. We further

#### TABLE 2.

PSC-Driven Resource Use

|  | Unit Costª | Barrier Alone |             | <b>Barrier &amp; Components</b> |            |            |          |
|--|------------|---------------|-------------|---------------------------------|------------|------------|----------|
|  |            | Mild          | Moderate    | Severe                          | Mild       | Moderate   | Severe   |
| PSC severity   |            | 25%           | 55%         | 20%                             | 25%        | 55%        | 20%      |
| Self-care  |            |               |             |                                 |            |            |          |
| % of individuals attempting self-care                              |            | 100           | 100         | 100                             | 100        | 100        | 100      |
| % use of barrier changes (# days) <sup>b</sup>                     |            | 175 (14)      | 350 (7)     | 350 (3)                         | 175 (14)   | 350 (7)    | 350 (3)  |
| Clinical utilization   |            |               |             |                                 |            |            |          |
| ET/WOC nurse consult (first)                                       | \$53°      | 25%           | 100%        | 100%                            | 100%       | 100%       | 100%     |
| Add ostomy component   |            |               |             |                                 | 100%       | 100%       | 100%     |
| % use of barrier changes (nurse directed)<br>(# days) <sup>b</sup> |            | 175 (7)       | 175 (23)    | 350 (27)                        | 175 (7)    | 175 (7)    | 175 (14) |
| Stoma powder   | \$16       | 100%          | 100%        | 100%                            | 100%       | 100%       | 100%     |
| Skin protectant film (# units)                                     | \$1.57     | 100t% (3.5)   | 100% (11.5) | 100% (27)                       | 100% (3.5) | 100% (3.5) | 100% (7) |
| Hydrocolloid sheet (# units)                                       | \$8.36     |               | 100% (2)    | 100% (4)                        |            | 100% (1)   | 100% (2) |
| Topical corticosteroid   | \$10       |               | 10%         | 20%                             |            | 5%         | 10%      |
| Topical antifungal   | \$12       |               | 50%         | 50%                             |            | 25%        | 25%      |
| ET/WOC nurse consult (second)                                      | \$53°      |               | 70%         | 80%                             |            | 35%        | 40%      |
| ET/WOC nurse consult (third)                                       | \$53c      |               |             | 50%                             |            |            | 25%      |

Abbreviation: PSC, peristomal skin complication.

<sup>a</sup>Manufacturer's Suggested Retail Price, British Columbia; 2014 Canadian dollars.

<sup>b</sup>Versus an uncomplicated ostomy average of twice-weekly barrier changes.

<sup>c</sup>BC Nurse Union wage grid (www.bcnu.org/contracts-bargaining/documents/NBA\_Wage\_Grid.pdf).

assume that this self-directed intervention is enough to enable skin healing for most (75%) individuals with mild PSCs. These individuals will then return to their baseline (twice-weekly) frequency of barrier changes after 14 days. The remaining individuals (25%) with mild PSCs are assumed to consult an ET/WOC nurse at the end of the first 14 days. In the Barrier Alone scenario, adding an ostomy component (eg, skin barrier ring or seal, stoma paste) to individualize the fit of an ostomy barrier is not an option. Instead, our model assumes that the ET/WOC nurse will suggest continuing to change the ostomy barrier everyother-day for 1 more week (total of 21 days to healing) and will recommend that all individuals use a stoma powder and skin protectant film with each barrier change to treat the irritated peristomal skin.

Individuals with a moderate PSC in the Barrier Alone scenario are assumed to respond initially by changing their barriers daily (350% of their usual use) for an average of 7 days (Table 2). Self-directed care notwithstanding, we assume that all individuals with a moderate PSC will eventually consult an ET/WOC nurse, who will suggest moving to an everyother-day barrier change schedule for 23 days; recommend use of a stoma powder and skin protectant film with each barrier change to treat irritated skin; and direct use of a hydrocolloid sheet, topical corticosteroid, and/or topical antifungal to help skin healing. Most individuals (70%) with a moderate PSC will have a second visit with an ET/WOC nurse. The model assumes conservatively that a moderate PSC will heal within a 30-day window (7 days of self-care + 23 days of ET/WOC nurse-directed care), after which the individual will return to a baseline schedule of barrier changes.

Similarly, individuals with severe PSC are assumed to attempt self-management of leakage and skin irritation by increasing the frequency of barrier changes to once daily, although we envision that the severity of their wounds will motivate them to seek clinical attention sooner (after 3 days) than individuals with less severe PSCs (Table 2). For these individuals, we assume that the ET/WOC nurse will suggest a schedule of once-daily barrier changes for 27 days; recommend use of a stoma powder and skin protectant film with each barrier change to treat irritated skin; and direct use of a hydrocolloid sheet, topical corticosteroid, and/or topical antifungal to aid skin healing. Most individuals (80%) with a severe PSC will have a second visit with an ET/WOC nurse; some (50%) will require a third visit. As before, the model assumes conservatively that severe PSCs will heal within a 30-day window (3 days of self-care + 27 days of ET/WOC nurse-directed care), after which the affected individual will return to a baseline schedule of barrier changes.

In the Barrier and Components scenario, we assume that individuals experiencing PSCs will, as before, respond by changing their ostomy barriers more frequently than usual (Table 2). However, in contrast to the Barrier Alone scenario and in keeping with our premise that ostomy components are used with clinical oversight, our analysis assumes that all individuals who experience PSC will consult an ET/WOC nurse. The nurse will recommend a clinically appropriate component to stop leakage by improving the individual fit/adhesion of the ostomy barrier (Table 3). We assume that the ET/WOC nurse will still direct individuals to increase their barrier change frequency to allow the PSCs to heal but, because the component improves barrier fit/adhesion, individuals will be able to resume their baseline barrier change schedule after an average of 7 (mild/moderate PSCs) or 14 (severe PSCs) days of specialist nurse-directed care. Furthermore, the analysis assumes that individuals in the Barrier and Components scenario make short-term use of a skin barrier powder and skin barrier protectant film with each barrier change to treat broken peristomal skin. However, because of the ostomy component in this scenario, we assume the ET/WOC nurse will work with the patient to break the leakage cycle, resulting in relatively less use of hydrocolloid sheets, topical corticosteroids, topical antifungals, and follow-up visits compared to their counterparts in the Barrier Alone scenario. In addition, we assume that individuals within the Barrier and Component scenario will use components for the duration of the model and change the component each time they change their ostomy barriers.

Our ET/WOC nurse panel estimated that the use of an ostomy component following a first PSC reduces an individual's risk of having a subsequent PSC by 80%. Individuals who experience a second (or third) PSC event are assumed to generate all PSC-related costs, including the use of a second (or third) ostomy component for the

#### TABLE 3.

#### **Ostomy Components**

| Ostoniy Components            |                          |                           |         |           |
|-------------------------------|--------------------------|---------------------------|---------|-----------|
| Ostomy Component <sup>a</sup> | % Of Cohort <sup>b</sup> | Cost/Package <sup>c</sup> | # Units | Unit Cost |
| Skin barrier ring or seal     | 66                       | \$76.50                   | 10      | \$7.65    |
| Barrier strips                | 1                        | \$31.50                   | 10      | \$3.15    |
| Paste                         | 7                        | \$19.00                   | 30      | \$.63     |
| Adhesive releaser             | 26                       | \$32.50                   | 30      | \$1.08    |

<sup>a</sup>The model assumes that components are changed with each barrier change. <sup>b</sup>Manufacturer's Suggested Retail Price, British Columbia; 2014 Canadian dollars. duration of the model but receive no additional preventive benefit from the use of the second (or third) component.

The maximum number of PSC events allowed in the model is 4. Those experiencing a fourth PSC event are assigned a 1-time, macro-cost of \$1200, which is intended simply to acknowledge that individuals with chronically occurring PSCs will likely require referral for more complex management. This fixed cost does not vary by modeled scenario (Barrier Alone; Barrier & Components) or by the elapsed time between the start of therapy and the occurrence of the fourth PSC event.

#### Health-Related Quality of Life

An important outcome of any clinical intervention is the change it makes-for better or worse-in a person's perceived state of well-being. Traditionally, preferences for certain health states are measured using an interval scale, where a score of 1.0 indicates an optimal level of health and well-being ("perfect health") and 0.0 indicates the worst health status possible. Each health state in between is assigned a preference weight, or utility, ranging from 0.0 to 1.0. If someone experiences an improvement in his or her well-being, we say that his or her utility has increased. If well-being declines, we say that his or her utility has decreased. Quality adjustments allow for differences in morbidity effects between alternate interventions being assessed. In the present context, the baseline (reference) utility is 1 day with uncomplicated ostomy (1 quality-adjusted life day, or QALD). An unpublished study estimates the utility decrements, or "disutilities," that are associated with a first, second, or third PSC.14 These disutilities are subtracted from the baseline because they decrease the individuals' health-related quality of life by a small amount; this effect persists daily until the PSC heals.

For example, individuals with healthy peristomal skin (no PSC) are assumed to have a QALD of 0.754 (ie, about 75% of the quality of life they would have in 1 day of perfect health). Having a mild PSC reduces that quality of life by 0.0057 units, every day, for the duration of the PSC. Thus, the daily quality of life for an individual with

| TABLE 4.                                       |             |                   |
|--|-------------|-------------------|
| Health-Related Quality of Life <sup>a</sup>    |             |                   |
| Health State                                   | QALD        | QALD<br>Decrement |
| Uncomplicated ostomy (reference case)          | 0.754       |                   |
| Mild PSC                                       |             | 0.057             |
| Moderate PSC                                   |             | 0.107             |
| Severe PSC                                     |             | 0.165             |
| Fourth PSC                                     |             | 0.165             |
| Abbreviations: PSC, peristomal skin complicati | on; QALD, q | uality-adjusted   |

life day. <sup>a</sup>Reprinted with permission from Nichols.<sup>14</sup> a mild PSC is (0.754 - 0.0057 =) 0.647 (Table 4). The exception is that individuals experiencing a fourth PSC, the maximum number allowed in the model, are assumed to accrue 0.647 QALD (0.754 - 0.165), every day, not just for the duration of the PSC, but for the duration of the modeled year.

#### Running the Model

Running the model considers all of the baseline assumptions together to simulate the 1-year experience of individuals in each scenario. During this period, the model keeps track of individuals' use of ostomy supplies, PSC events, and direct clinical care costs, as well as the number of QALD generated. At the end, the model compares the total number of PSC events in each clinical management scenario (Barrier Alone; Barrier & Components), relative utilization of ostomy supplies and direct clinical care costs, and the number of QALD arising as a result of the different strategies.

#### Model Validation

Technical validity was assessed by a thorough quality check of programming and by setting inputs to extreme values. For example, if the annual rate of PSCs is set to 0%, then the model should report 0 PSC events; if 100% of PSC events are assumed to be severe, then the model should calculate no utilization for mild and moderate PSCs; and so on. In addition, 1-way sensitivity analyses were conducted on user-modifiable inputs to test the robustness of modeled observations.

# Results

When compared to the Barrier Alone scenario, the Barrier and Components scenario resulted in 130 fewer PSC events (520 vs 650) over the course of 12 months (Table 5). Specifically, fewer individuals had repeat PSCs in the Barrier and Components scenario compared to those in the Barrier Alone arm (3% vs 14%). Individuals in the Barrier and Components scenario accrued 1043 more QALD over the course of the modeled year compared with their counterparts in the Barrier Alone scenario (270,538 vs 269,495). Thus, each PSC event avoided via the use of ostomy components yielded, on average, 8 additional QALD during the modeled year (1043 QALD gained ÷ 130 PSC events avoided). The incremental resource use for ostomy components in the Barrier and Components scenario (\$224) was offset by lower average resource use for supplies (barriers; pouches) (\$2061 vs \$2109) and lower clinical utilization (\$54 vs \$91) than the Barrier Alone scenario. Overall, we found that per capita annual resource use was about 6.3% (\$139) higher in the Barrier and Components scenario (Table 5).

#### Sensitivity Analysis

One-way sensitivity analyses on user-modifiable input variables support the robustness of model findings. Our analysis is most sensitive to assumptions about (1) the increased use of ostomy supplies among individuals who

| Outcome   | <b>Barrier Alone</b> | <b>Barrier &amp; Components</b> | Difference |  |
|---|----------------------|---------------------------------|------------|--|
| # Individuals   | 1000                 | 1000                            |            |  |
| Effectiveness   |                      |                                 |            |  |
| Total PSC events  | 650                  | 520                             | 130        |  |
| Individuals with 1 or fewer PSCs                          | 86%                  | 97%                             |            |  |
| Individuals with more than 1 PSCs                         | 14%                  | 3%                              |            |  |
| Quality-adjusted life days <sup>a</sup>                   |                      |                                 |            |  |
| Full cohort   | 269,495              | 270,538                         | 1043       |  |
| Total resource use (average, per individual) <sup>b</sup> |                      |                                 |            |  |
| Ostomy supplies (barriers; pouches)                       | \$2109               | \$2061                          | (\$48)     |  |
| Ostomy components   |                      | \$224                           | \$224      |  |
| Clinical utilization                                      | \$91                 | \$54                            | (\$37)     |  |
| Total   | \$2200               | \$2339                          | (\$139)    |  |

<sup>a</sup>Based on a 360-day modeled year.

<sup>b</sup>2014 Canadian dollars.

experience PSCs (ie, the additional frequency with which barriers are changed coupled with time to healing) and (2) the cost of ostomy components. All other things being equal, individuals with PSCs for whom ostomy components are unavailable will consume relatively more ostomy supplies (barriers; pouches) and have worse outcomes (more repeat PSC events; fewer QALD) over the course of a year. Individuals with PSC for whom ostomy components are used to resolve issues of barrier fit and adhesion will have component acquisition costs (offset in whole or in part by the use of relatively fewer barriers/pouches) as well as better outcomes (fewer repeat PSC events; more QALD) over the course of a year.

# Discussion

Our analysis of 1000 hypothetical individuals with an ostomy estimated that the use of components following a first PSC would result in 130 fewer PSC events over the course of 1 year versus PSC management without components. In this analysis, the costs of ostomy components were offset by lower resource use for other ostomy supplies (barriers; pouches) and lower clinical utilization to manage PSCs. Overall, annual average resource use was about 6.3% (\$139 per individual) higher when ostomy components were used with clinical oversight, compared to a strategy of managing PSCs without ostomy components. Each PSC event avoided via the use of ostomy components yielded, on average, 8 additional QALD over the modeled year.

Our analysis was most sensitive to assumptions about the increased use of ostomy supplies (barriers; pouches) among individuals who experience PSCs (ie, the additional frequency with which barriers are changed coupled with the time to healing) and the cost of ostomy components. In general, our model demonstrates that when ostomy components are used successfully to address issues of barrier fit/adhesion, individuals will (1) generate component acquisition costs that are offset in whole or in part by the consumption of relatively fewer ostomy supplies and (2) have better outcomes (fewer repeat PSC events; more QALD) over the course of a year compared to a strategy of PSC management without components.

This analysis is not without limitations. First, there is little published evidence from which to draw baseline model inputs. In its absence, we relied heavily on the experience of a panel of ET/WOC nurses in active practice. Our analysis would benefit from stronger, evidence-based inputs. Related to this is the observation that ostomy practice patterns (eg, usual barrier change schedules; standards of care for PSC) vary nationally, regionally, and even locally, making it impossible to create a single, broadly applicable set of baseline assumptions. Nevertheless, the decision model we constructed applies a consistent theoretical framework to clarify immediate and downstream cost and outcome tradeoffs between alternative therapeutic approaches. By design, the baseline assumptions of a model are easily changed in light of new information and/or to meet the needs and local clinical practices of decision makers.

Second, our model takes a conservative position regarding the severity mix of PSCs; specifically, that PSC severity will remain the same whether or not ostomy components are used. However, to the extent that ostomy components prevent leakage, as they are designed to do, it is conceivable that any subsequent PSCs may be milder than would be anticipated if PSCs were managed without components.

Third, depending on the circumstances, an ET/WOC nurse evaluating a leakage-related PSC might not suggest adding an ostomy component but, instead, might appropriately recommend use of a differently sized barrier, or a switch from a flat-barrier to a convex-barrier in order to improve the barrier's seal with the abdominal skin. Our analysis does not consider these therapeutic options, which also have the potential to reduce the recurrence of PSCs for some individuals, albeit with a higher unit cost per barrier.

Finally, the model assumes conservatively that all PSCs are resolved within a 30-day window. However, at least one cross-sectional study found that, in 76% of patients with PSCs, the issues took more than 3 months to resolve.<sup>3</sup> Indeed, without components to prevent recurring leakage, stepping up the frequency of barrier changes is one of the few ways individuals have to manage and prevent PSCs. For some, the increased use of ostomy supplies (barriers; pouches) triggered by a first PSC may become their "new normal" rather than an acute intervention. When this is the case, the additional use of ostomy supplies will quickly exceed the cost of using an ostomy component to improve barrier fit/adhesion from the outset, again adding strength to our conclusions.

# Conclusions

Ostomy components used with clinical oversight may prevent PSC by improving barrier fit/adhesion. In our analysis, (1) acquisition costs for ostomy components were offset in whole or in part the use of fewer ostomy supplies to manage PSCs and (2) use of ostomy components to prevent PSCs produced better outcomes (fewer repeat PSC events; more QALD) over 1 year compared to not using components.

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