

# The Health-Related Quality of Life (HRQoL) Associated with Ostomy Appliances and Features

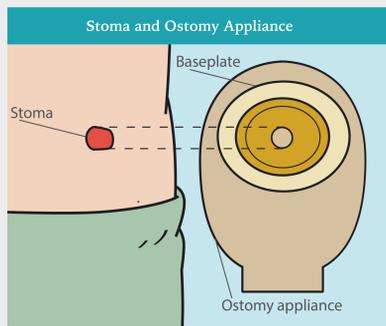
## A time trade-off (TTO) internet experiment

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### Introduction

- An 'ostomy' is a surgically created opening in the body for the discharge of body wastes
- A 'stoma' is the actual end of the small or large intestine (or ureter) that protrudes through the abdominal wall
- An 'ostomy appliance' is a medical prosthetic device that is used for the collection of output from a stoma
- Undergoing an ostomy surgery, and consequently living with an ostomy appliance is known to have a significant impact on the life of the individual<sup>11</sup>
- Consequently, ostomates experience a lowered quality of life (QoL)<sup>12</sup>



#### Health-related quality of life (HRQoL) issues arising from living with an ostomy appliance<sup>12-71</sup>

- Fear of leakage from the appliance
- Ballooning (trapped intestinal gas inflating the bag)
- Peristomal skin complications (PSCs)
- Aversion to the appearance of the appliance: body image
- Limited choice of clothing and physical activity
- Isolation from social activities and limited social functioning
- Anxiety, depression, lack of sleep

#### Many HRQoL issues can be resolved by addressing leakage, ballooning, PSCs, appliance appearance, comfort and fit and the confidence of the individual.

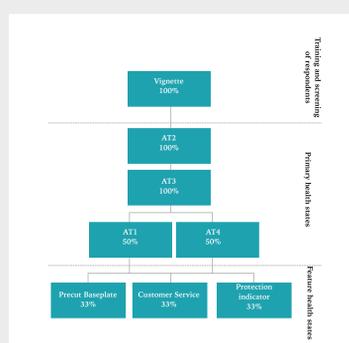
- Differences between ostomy appliance technologies have until now only been documented using condition-specific tools
- These results are not applicable in standard economic evaluations which require a common metric for measuring outcomes, such as QALY-values

### Objectives

To measure the incremental (HRQoL) associated with different ostomy appliance technologies and features for a British General Population (BGP) and a Swedish Patient Population (SPP), using a time trade-off (TTO) internet experiment

### Methodology

- An internet-based TTO survey was used to obtain HRQoL associated with eight health states defined by four ostomy appliance technologies and three features applicable to ileostomy and colostomy devices. Both a BGP and a SPP were investigated



- Eight health states in the study:
  - 1 Vignette health state
  - 4 Ostomy appliance health states
  - 3 Feature health states

#### Ostomy Appliance Health States

	Appliance Technology 1 (AT1)	Appliance Technology 2 (AT2)	Appliance Technology 3 (AT3)	Appliance Technology 4* (AT4)
Adhesive technology**	Hydrocolloid adhesive	Double layered hydrocolloid adhesive	Elastic hydrocolloid adhesive	Next generation adhesive
Prefilter technology	Single located prefilter	Improved single located prefilter	Multi-inlet prefilter	Multi-inlet prefilter
Bag technology	Standard Bag	Standard Bag	Discrete Bag	Discrete Bag

AT = Appliance Technology.  
\*Hypothetical Health State.  
\*\*The adhesive technology was split in three attributes: comfort and fit; leakage confidence and incidence of skin problem

#### Feature Health States

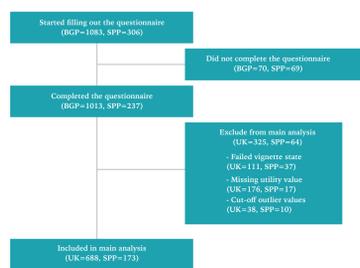
Pre-cut Baseplates	The baseplate hole is customized from the factory
Customer Service	Access to a customer service centre with trained staff
Protection Indicator	A built-in indicator that reduces leakage and peristomal skin complications

- Statistical analyses were performed using SAS® version 9.4 statistical software
- Bootstrapping was used to simulate standard errors and confidence intervals for the mean utility values. 10,000 bootstrapping iterations were performed for each mean utility value
- The study excluded 5% of outliers (2.5% from each distribution tail) based on the individual utility values to ensure the robustness of the results
- A sensitivity analysis investigated the impact of outliers on the incremental utility at four cut-off limits (0%, 1%, 5% and 10%)

### Results

- Respondents were as follows:
  - British General Population (BGP): 1,013 healthy individuals, recruited through a commercially available e-mail panel
  - Swedish Patient Population (SPP): 237 ileostomy/colostomy users, recruited through a database of end-users maintained by Coloplast A/S, Sweden

#### Patient Flow



#### Demographics of Respondents Included in the Main Analysis

	BGP (n=688)	SPP (n=173)
Mean Age (years) ± SD	45.9 ± 13.5	64.5 ± 11.4
Sex % (Male/Female)	51.8%/48.1%	49.7%/50.2%
Years with ostomy, mean years	N/A	12.95
Type of ostomy		
• Colostomy, % (n)	N/A	48.55 (84)
• Ileostomy, % (n)	N/A	49.13 (85)
• Don't know, % (n)	N/A	2.31 (4)

Abbreviations: BGP=British General Population; SPP=Swedish Patient Population, n=number of respondents; SD=standard deviation; N/A=not applicable.

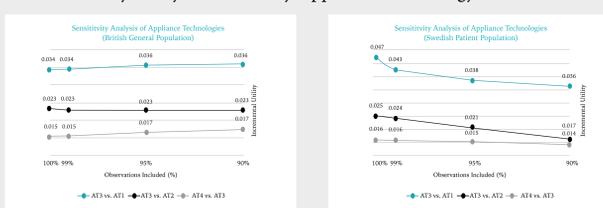
Results of the main utility analysis for both the BGP sample and the SPP sample.

#### Incremental Utility Value (CI: 95%)

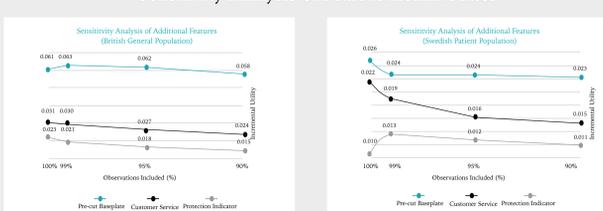
	BGP sample	SPP sample
Ostomy Appliance Health States		
• AT 3 vs. AT 1	0.036 (0.024-0.047)	0.038 (0.023-0.054)
• AT 3 vs. AT 2	0.023 (0.016-0.030)	0.021 (0.011-0.031)
• AT 4 vs. AT 3	0.017 (0.007-0.025)	0.015 (0.004-0.027)
Feature Health States		
• Pre-cut baseplate	0.027 (0.018-0.037)	0.016 (0.001-0.033)
• Customer Service	0.018 (0.008-0.028)	0.012 (0.001-0.024)
• Protection indicator	0.062 (0.047-0.077)	0.024 (0.007-0.041)

BGP=British General Population; SPP=Swedish Patient Population; CI=Confidence interval; AT=Appliance technology.

#### Sensitivity Analysis of Ostomy Appliance Technology Health States



#### Sensitivity Analysis of Feature Health States



#### Sensitivity Analysis

- BGP sample: the different cut-off limits (0%, 1%, 5% and 10%) showed an impact on utility values between 0 and 0.002 on the ostomy appliance health states, and between 0.005 and 0.008 on the feature health states
- SPP sample: the different cut-off limits (0%, 1%, 5% and 10%) showed an impact on utility values between 0.002 and 0.011 on the ostomy appliance health states, and between 0.003 and 0.007 on the feature health states
- Overall, the BGP outliers had less impact on the incremental utility values compared to the SPP outliers, which generally increased the incremental utility values

### Discussion

- Creation of an ostomy is known to create many challenges in terms of quality of life and functioning.<sup>28</sup> In a recently reported study, it was observed that in patients operated for rectal cancer, those with a permanent stoma experienced inferior HRQoL compared to patients without a stoma.<sup>29</sup> This supports previous studies which also conclude that stoma patients experience decreased HRQoL
- Novel technologies and features in the ostomy appliances improving leakage, ballooning, PSCs, appliance appearance, comfort and fit and the confidence of the individual may improve the associated HRQoL of the ostomate
- These new technologies and features are bound to increase the cost of the device, and consequently affect reimbursement. A study from 2015 reported preference and willingness-to-pay for these improvements using a discrete choice experiment<sup>31</sup>
- However, for comparing health technologies, health technology assessment (HTA) agencies and bodies like the National Institute for Health and Care Excellence (NICE) prefer cost-utility analyses derived using validated generic instruments such as EQ-5D. These generic instruments have inherent disadvantages such as insensitivity to small, but potentially relevant changes in HRQoL. They also do not measure all categories of benefit such as those related to the administration of the treatment itself.<sup>101</sup>
- The inclusion of TTO experiments in addition to the generic instruments can provide a more comprehensive picture of utility increments in novel health technologies such as ostomy devices
- The present study investigated the utility impact of different ostomy technologies and features in a BGP and a SPP, using an internet experiment. This study showed statistically significant improvements associated with both ostomy appliance technologies and features, which confirms the notion that different preference values exist for different ostomy appliances
- This study is the first to apply the TTO method for comparing HRQoL among different ostomy appliance technologies

### Conclusions

- The present internet-based TTO study showed that addition of these technologies and features of ostomy appliances, as represented by different health states, showed statistically significant improvements in HRQoL
- The health states for ostomy appliances showed an incremental utility ranging from 0.017-0.036 in a British General Population, and from 0.015-0.038 in a Swedish Patient Population. Only minor differences were observed in the incremental utility values between the two populations
- The sensitivity analysis showed that the BGP outliers had little impact on the incremental utility values, while the SPP outliers increased the incremental utility values
- The TTO method can be used to measure HRQoL related to ostomy appliances

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