

# DialogueStudy Press Release

## New ostomy study: Leakage and skin irritation significantly reduced through evidence-based nursing

A new global study conducted among 3017 users of ostomy products confirms the correlation between leakage and peristomal skin condition. The study, which is the largest real-life study within ostomy con-ducted to date, also shows that leakage and skin irritation can be significantly reduced through evidence-based nursing – a mix of global ostomy tools based on clinical research combined with the enterostomal therapy nurse’s own experiences.

The Global DialogueStudy was carried out in 18 countries around the world and more than 500 nurses were in-volved in recruiting patients and monitoring and reporting observations and findings. The consolidated data from all 18 countries was presented in November at a special international event with more than 200 healthcare professionals in attendance.

Janet Stoia Davis, a registered nurse for more than 34 years and an international lecturer on ostomy issues, ex-plains the survey process:

“A clinical study within ostomy typically has around 100 participants or less, so the results of the DialogueStudy, providing data on over 3000 users will have a tremendous impact. This is the first time we have this many healthcare professionals and users in so many countries involved.”

The 500 nurses involved in the DialogueStudy were all introduced to the use of the Ostomy Skin Tool and Sto-ma Quality of Life questionnaire, at the beginning of the process.

“The study shows that overall leakage was brought down from 90% to 60% through evidence-based nursing, which means relying on clinical data, on global tools and on the enterostomal therapy nurse’s knowledge and experience to choose the right product and treatment. A drop of 30% is impressive and exciting! By reducing the risk of leakage there is a significant improvement in the quality of life for the users - and as nurses, and es-pecially enterostomal therapy nurses, our goal is to have the stoma fit into the lives of our patients not to let their lives fit around their stoma. The DialogueStudy has provided us with a lot of data to pass on to both our colleagues and individuals living with a stoma.”

The DialogueStudy was carried out by Coloplast, who also hosted the special event at their Danish headquarter. Coloplast’s SenSura products were part of the study and combined with evidence-based nursing, the SenSura products showed the best results.

According to Janet Stoia Davis, the DialogueStudy is a great example of a supplier of products working together with healthcare professionals in order to provide better care, but she also has a challenge for Coloplast and other suppliers of ostomy products.

“The DialogueStudy shows us the importance of knowledge – the importance of educating nurses on an on-going basis. This approach can decrease leakage significantly; however, the study also shows us that it cannot completely eradicate the risk of leakage. So we also need a continuous focus on product development. People have different body types and therefore different needs, so we need to continuously develop new products to meet these needs.”

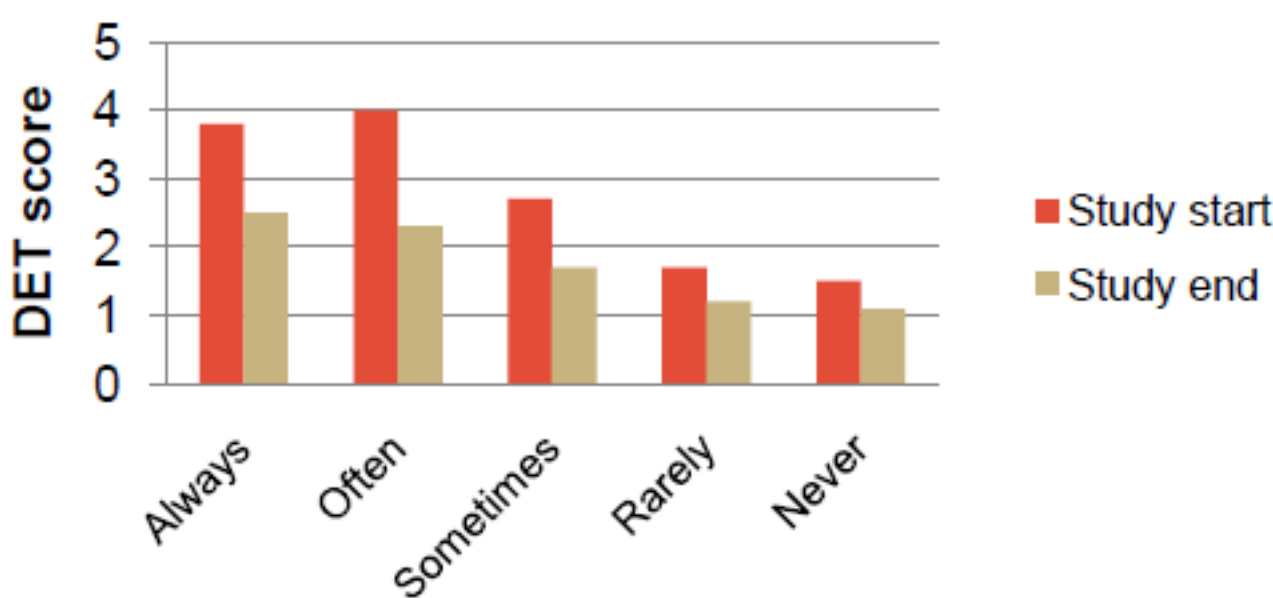
## Backgrounder

- The Global DialogueStudy is the largest real life study within ostomy conducted to date
- The study focuses on monitoring the skin condition around stomas - an area prone to skin disorders due to extra stress put on the skin - over a 6-8 week period
- The DialogueStudy has lasted four years (2006 – 2010)
- 3017 ostomy patients participated and over 500 nurses have been involved in monitoring and reporting the study observations
- It is an international study covering 18 countries: Denmark, the UK, Germany, France, Poland, the Netherlands, Italy, Spain, Portugal, Iceland, the US, Canada, Argentina, Japan, Australia, South Korea, the Czech Republic and Slovakia

Country	Number of participants	Country	Number of participants
USA	701	Japan	110
France	522	Argentina	104
Poland	261	Denmark	100
Germany	166	Netherlands	94
United Kingdom	140	Czech Republic	92
Portugal	136	Iceland	73
South Korea	132	Slovakia	61
Spain	131	Canada	43
Italy	115	Australia	36
		<b>TOTAL</b>	<b>3,017</b>

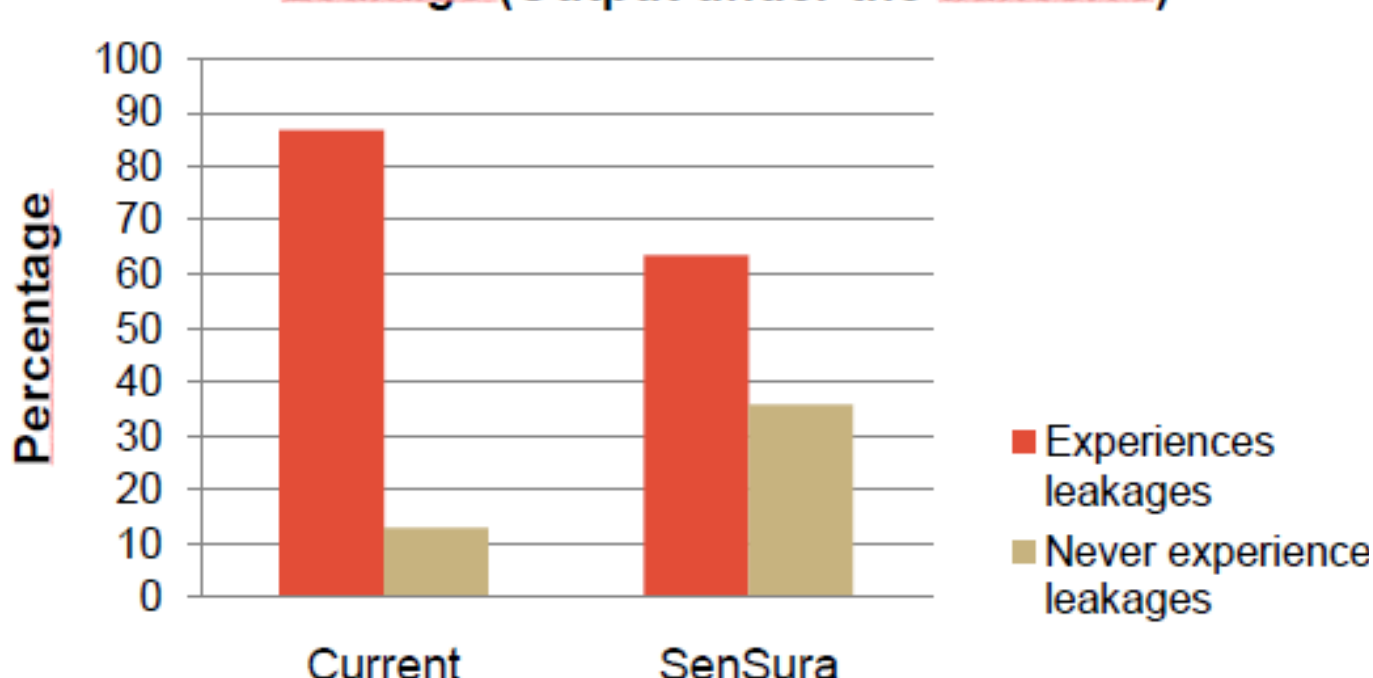
- The consolidated study results were presented at the Dialogue Global Meeting 12-13 November 2010 in Coloplast’s Danish Head Office outside Copenhagen
- The study confirms the correlation between leakage and peristomal skin condition:

### Frequency of output under the adhesive (leakage)



- Overall the leakage was brought down from 90% to 60% through evidence-based nursing and the use of a SenSura ostomy appliances:

### Leakage (Output under the adhesive)



- The tools used by the nurses include the Ostomy Skin Tool and Stoma Quality of Life questionnaire
- The Ostomy Skin Tool provides enterostomal therapy nurses with a ‘DET score’ (discolouration, erosion and tissue) and a diagnostic guide. It also provides the nurses with a common language to describe peristomal skin condition
- The Stoma-QoL questionnaire is a simple, validated questionnaire that specifically assesses quality of life, including changes over time. It includes 20 questions and provides a QoL score between 0–100 (100=best)
- The DialogueStudy showed that some patients still have leakage problems, this could be due to a chal-lenging body type (scares, dips or creases in the peristomal skin area)
- Janet Stoia Davis is American – she has over 25 years experience in WOC nursing - certified as a CWOE in 1985. Her career as a registered nurse began in 1976 with a focus on critical care nursing. In 1996, she began a private WOC practice, first as a partnership and presently as sole proprietor. As a WOCN consultant she practices across the continuum of care, with a focus on acute care, outpatient ostomy clinics and long term care. In addition, Janet lectures locally, nationally and internationally.