How to use the Risk Factor Model

A consensus-based guideline to support prevention of peristomal skin complications (PSC)

Coloplast | Professional

How to use the Risk Factor Model

The Risk Factor Model should be used as a tool for assessing the specific needs of individual patients in daily practice. By managing these risks and initiating the appropriate intervention, it's possible to prevent the physical burden of peristomal skin complications (PSC) and improve life for people living with a stoma.

1

Consult with your patient

To prevent leakage and PSC, regular risk assessment is crucial for every patient – no matter if they have had surgery recently or several years ago.

2

Check the Risk Factor Model

In consultation with your patient, go through the 3 risk categories and check which apply to their physical needs and personal situation.

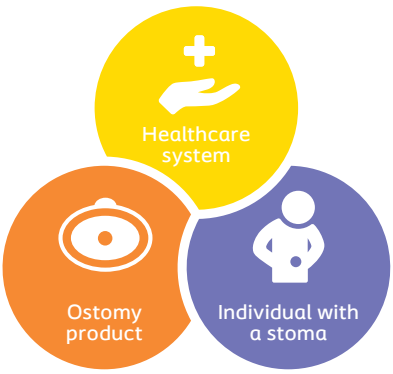
3

Assess their personal risk

Use the model to create a specific assessment of any risks relevant for the individual patient, and then initiate the appropriate intervention to prevent leakage and PSC.

Risk Factor Model

Identify relevant risk factors to prevent peristomal skin complications



Patient name _____ Date _____

Healthcare system

Standard of stoma care

- ☐ **Pre-operative guidelines**
  Stoma marking and preparation of patient for surgery and life post-surgery etc.
- ☐ **Surgical guidelines**
  Best practice for creating stomas for best possible patient outcome etc.
- ☐ **Care guidelines**
  High-quality post-operative training and follow up etc.
- ☐ **Societal view of people with chronic conditions**
  How local culture, governance and values influence life post-stoma etc.

Access to appropriate support/ products

- ☐ **Post-discharge programmes**
  Health insurance's / healthcare system's impact on access to follow-up programmes etc.
- ☐ **Appropriate product type and quantity**
  Access to appropriate products for output type/volume/body profile, Health insurance/reimbursement system's impact on product allowances.

Level of education in stoma care and surgical procedures

- ☐ **Healthcare professionals**
  General level of education; access to further education; ability to teach stoma management and in surgical procedures.

Individual with a stoma

Physical characteristics

- ☐ **Peristomal body profile**
  Regular/inward/outward profile and the need for products/pouching system to provide the right fit etc.
- ☐ **Stoma construction**
  Stoma height and location on adhesion and fit etc.
- ☐ **Stoma/Output types**
  Output type, consistency and volume.
- ☐ **Skin properties/conditions**
  Sensitive/dry/fragile/greasy/oily skin, creases, scars, folds, wounds, skin- or underlying diseases.
- ☐ **Medication/treatment**
  Side effects from immunosuppressive treatment, steroids, radiation therapy and chemotherapy etc.
- ☐ **Disabilities**
  Impact of poor eyesight, low hand dexterity, wheelchair bound, etc.

Mental capabilities

- ☐ **Self-consciousness /Self-care**
  Denial/lack of coping skills which impact stoma management, ability to adapt to new life conditions.
- ☐ **Stoma management**
  Ability to perform stoma care routines – technique and routines in personal stoma care practice.

Social situation

- ☐ **Support**
  Network of family and friends who can provide help etc.
- ☐ **Standard of living**
  Living conditions and level of income that may impact stoma management.

Ostomy product

Usage

- ☐ **Fit to body profile**
  Fit of the pouch system to adapt to the body profile etc.
- ☐ **Fit to stoma shape**
  Fit of the size/pre-cut hole to the stoma etc.
- ☐ **Application/removal**
  Ease of application/removal of the pouching system etc.
- ☐ **Wear time**
  Does the chosen pouch system match recommended and preferred wear time?
- ☐ **Range and type of products**
  Product accommodating individual needs, body profiles and type of stoma/output etc.

Technical properties

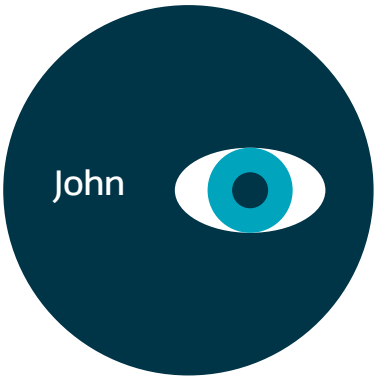
- ☐ **Adhesive properties**
  Adherence, moisture absorption, erosion etc.
- ☐ **Filter performance and capacity**
  Retains solids/liquids in pouch; prevents ballooning or pancaking etc.

Notes _____

The Risk Factor Model consists of three categories for assessing the risk of skin complications. Each category has a list of subcategories which are defined in broad terms and include several guideline areas that may affect life for people living with a stoma. For example, surgical guidelines for procedures that affect the formation of a stoma can make a difference to people's quality of life after surgery, as in the case of stoma marking. The related guidelines may differ from region to region, and the subcategories must always be responded to in accordance with local guidelines and regulations.

Case example: John

This real-life case is an example of how the Risk Factor Model can be used to make risk assessments of patients in daily practice. Using the Risk Factor Model as a guide, potential issues can be identified to prevent peristomal skin complications.



What are John's risks?

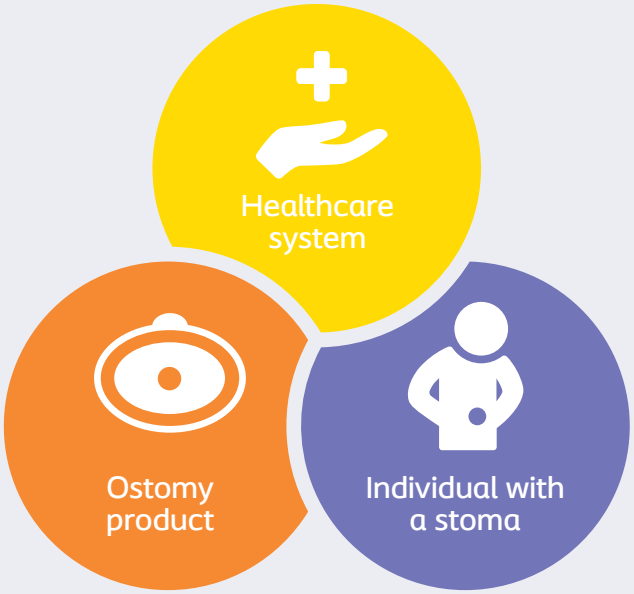
He has a permanent ileostomy

Age:	41 years old.
Personal life:	Married with a very supportive wife.
Physical characteristics:	Skinny due to weight loss during the past five months.
Medical history:	Diagnosed at age 16 with Crohn's disease. 3 years ago, half the colon and a part of the ileum removed. 4 months ago, colon removed but rectum preserved.
Stoma marking:	Performed prior to surgery.
Stoma position:	Corresponds to marking – ileostomy is circular.
Ostomy product:	Flat 2-piece with a pre-cut hole and open bag. John uses pieces of a ring or protective seal to even out scars and creases and provide extra security.
Output:	Liquid to watery output 7 on the Bristol stool scale.
Covered by reimbursement:	Receives products from a specific manufacturer (defined by a current tender).
Monthly product allowance:	30 baseplates – more if necessary (due to leakages). 30 large bags. 30 medium bags.
Discharge programme:	John is having immunosuppressive treatment and is followed closely by his gastroenterologist. He has access to a stoma care nurse, but he must contact her himself if he needs support.

Let’s work together to avoid peristomal skin complications

Peristomal Skin Complications
Risk Factors

Every stoma is unique, and every patient’s personal situation is different. Many factors can affect a person’s risk of experiencing PSC, and the Risk Factor Model helps in identifying these risks by dividing them into three categories:



Healthcare system

Risk factors can include:

- How do local culture and governance affect life with a stoma?
- What are the regional guidelines for stoma surgery?
- What are the pre- and post-operative regional guidelines?
- What products are available to the patient in their region?

Individual with a stoma

Risk factors can include:

- What is the patient’s peristomal body profile?
- What type of stoma does the patient have?
- What disabilities and care technique considerations does the patient have?
- What is the patient’s family and friends support network?

Ostomy product

Risk factors can include:

- How well does the product fit to the patients’s peristomal body profile?
- How well does the pouch system adapt to the peristomal body profile?
- How long is the wear time of the product?
- How easy is the product to apply and remove?

The Risk Factor Model consists of three categories for assessing the risk of skin complications. Each category has a list of subcategories which are defined in broad terms and include several guideline areas that may affect life for people living with a stoma. For example, surgical guidelines for procedures that affect the formation of a stoma can make a difference to people’s quality of life after surgery, as in the case of stoma marking. The related guidelines may differ from region to region, and the subcategories must always be responded to in accordance with local guidelines and regulations.

Why was the Risk Factor Model created?

For people living with a stoma, PSC can become part of a vicious cycle – leakage irritates the skin on the peristomal area, making it difficult for the product to adhere properly to the skin, which in turn leads to more leakage. This worsens the peristomal skin complications and often has a negative impact on the patient's quality of life.[1]

To break this cycle, it's important that every patient's risk of PSC is assessed on an individual basis. The Risk Factor Model was developed to help make risk assessments of patients in daily practice easier.

How was the risk factor model created?

A full systematic literature review of the risk factors associated with development of peristomal skin complications was conducted. Expert groups, including global and national COF* boards representing 18 countries, helped to identify, review and align on the risk factors. This resulted in the Risk Factor Model, which was put through an international consensus process using a modified Delphi process, involving more than 4000 responses from experts within ostomy care from 35 countries. This resulted in the final Risk Factor Model, which has also been ratified by an expert group and Global COF.

Who can the Risk Factor Model help?

The Risk Factor Model is designed to help healthcare professionals to assess the needs of individual patients – which in turn should help to improve the standard of care for every person living with a stoma.

How many patients can benefit?

- 88% of people using an ostomy product have peristomal skin complications.[2]
- 7 out of 10 personal consultations with stoma patients are related to leakage and skin complications.[3]
- Less than half of patients with PSC are aware of the problem, and only 16% seek treatment.[4]

* The Coloplast Ostomy Forum (COF) is where top experts (ostomy care nurses) from around the world come together to learn from each other and share their insights with Coloplast.

1. Rolstad, B. S. et al., PERISTOMAL SKIN COMPLICATIONS: PREVENTION AND MANAGEMENT, Ostomy/Wound Management 2004;50(9):68-77.
2. Ostomy Life Study 2019, Consumer survey, Coloplast, Data on file, PM-10499.
3. Ostomy Life Study 2019, Nurse survey, Coloplast, Data on file, PM-11947.
4. Nybæk, H. et al., Skin Problems in Ostomy Patients: A Case-control Study of Risk Factors, Acta Derm Venereol 2009; 89: 64–67.

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