Introduction

Stoma forming surgery can have extensive, negative impacts on a patient's psychological wellbeing (McGrogan and Proctor 2024). Fear and anxiety around public humiliation can lead ostomates to avoid circumstances where they might be at risk of a leak. This social isolation is linked with anxiety, depression and a loss of self-esteem (Grant, 2019). These negative effects can be diminished with interventions such as finding the best combination of products for each individual patient. Ensuring a leak-free experience for all patients will help to support physical, psychological and emotional wellbeing.

Heylo is a leakage notification system for patients with a stoma. It notifies them at the first sign of potential leakage and gives the patient a discreet warning via their mobile phone, to allow them time to change their pouch. Heylo is intended for patients whose psychological wellbeing is negatively affected by fear of leakage from their pouch, leading to social anxiety and isolation.

Patient eligibility criteria

Heylo will only be considered for patients presenting with significant emotional distress, affecting their daily activities due to fear of leakage. The patient should be established on the correct stoma products and be competent in their use. The patient should be made aware that discontinuation of Heylo may occur if they no longer meet the criteria. The Stoma Nurse Specialist will use their clinical judgement in conjunction with the following criteria before initiating Heylo:

- Ileostomy or colostomy with a type 5-7 stool consistency (not high output);
- 12 weeks post-surgery*;
- should not have had any leaks in the previous 4 weeks;
- has intact peristomal skin;
- has had no new, unmanageable skin conditions in the last 4 weeks;
- patients who score a minimum of 27/40 on questions 1 to 8 on the Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire (supportive tool to determine the impact on patient's quality of life)**;
- is using products that are compatible with Heylo (see manufacturer's instructions for use for more information);
- owns a smart phone, is competent in using it and is comfortable with carrying this around;
- has the dexterity and ability to apply the sensor layer and transmitter or has a significant other to assist;
- is able to read and understand English;
- is not currently pregnant or planning pregnancy;
- is aged 18 years old or over;
- has the ability and dexterity to apply the sensor layer and transmitter or has a significant other to assist;
- consents to name, email address and contact information being shared for data analysis;
- consents to having the stoma items prescribed by Nottinghamshire Appliance Management Service (NAMS);
- has no known sensitivity to acrylates.

*Heylo can be recommended to patients who are less than 12 weeks post-op, should there be a significant need for the product and all other criteria are met.

**Stoma Nurses may initiate Heylo for a patient who scores below the threshold, should the patient meet all other criteria, and should they feel that Heylo would have a positive impact on the patient's psychological wellbeing.

Product initiation

A starter pack is provided by Coloplast and includes a transmitter, charging cable, unit and 10 sensor layers. This supply is suitable for the patient to begin a trial for 7-10 days, depending on how frequently the patient changes their pouch. The patient will be advised to use no more than one sensor layer per day. For a patient to benefit from Heylo, they need to be using the product consistently and daily during the trial period.

Coloplast have a dedicated helpline specifically for patients using Heylo, and this is available should any faults arise with the equipment or products. The patient can find the contact details in their starter pack.

The initiating stoma team will review the patient within 14 days of starting the product – see below for further info.

First review (within 14 days)

The first review will be undertaken within 14 days of starting the product. Reviews will be undertaken by the stoma nursing team who initiated Heylo, unless the patient has been transferred to the care of NAMS Stoma Nursing. A general wellbeing consultation will be carried out to gauge how often the patient has used the product, if the product is meeting the patient's needs, and, using the Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire, to determine whether the patient's scoring has changed. This is to determine whether the patient can continue using Heylo.

Following this review, if a patient is to continue using Heylo, a prescription will be requested from NAMS (Nottinghamshire Appliance Management Service).

The Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire will be used to ascertain whether the product has had a positive effect on the patient's psychological and physical wellbeing. This would be demonstrated by a reduction in scoring, although it is worth noting that scores may remain unchanged at this point, due to the psychological impact leaking has on a patient.

Second review (within 2 months of initiation)

The Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire will be used to ascertain whether the product has had a positive effect on the patient's psychological and physical wellbeing and it would be hoped to see a reduction in scoring, although it is worth noting that, scores may remain unchanged at this point, due to the psychological impact leaking has on a patient.

6-month review (post-initiation)

A review will take place 6 months from the patient being initiated on Heylo and annually thereafter.

The Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire will be used to ascertain whether the product has had a positive effect on the patient's psychological and physical wellbeing and it would be hoped to see a reduction in scoring, although it is worth noting that scores may remain unchanged at this point, due to the psychological impact leaking has on a patient.

During any review, if Heylo no longer meets the needs of the patient, the product may be discontinued at any time.

Annual review (1-year post-initiation)

The Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire will be completed again as well as holistic assessment of wellbeing, product use and audit. Reviews will be carried out by NAMS or the stoma nursing team the patient is currently under.

Discontinuation of Heylo

Heylo may be discontinued at any time. Heylo can also be discontinued should a patient no longer meet the eligibility criteria, and/or the following:

- patient is finding it too difficult to use Heylo, transmitter or mobile phone app;
- patient experiences adverse reactions to Heylo;
- patient becomes sensitive to acrylates;
- patient has their stoma reversed;
- patient becomes pregnant, or plans to become pregnant;
- patient no longer has the dexterity and/or ability to apply the sensor layer and transmitter independently, or does not have somebody who can assist with this.

Repeat template monitoring/ ongoing prescribing

A patient will be advised that they will be issued with 30 sensor layers, to last a total of 30 days. Review of repeat templates for patients will be monitored by NAMS. The NAMS nursing team can amend the repeat template of Heylo sensor layers if/when needed.

Product Effectiveness

Effectiveness can be monitored by reviewing patients at the intervals suggested and by using the Stoma Leakage Notification System Suitability Assessment Tool for Nottinghamshire. Over time, the scores should decrease, which is a good indication of how Heylo can positively affect a patient, both physically and psychologically. Please bear in mind that even if the scores are decreasing, this does not indicate that the product should be removed from the patient's routine or repeat template. Heylo is a product that the patient may use long-term.

Auditing

NAMS propose to carry out auditing at 6-monthly intervals. They will collect data on cost-effectiveness, product usage, clinic appointments and impact on quality of life. Support is available from the hospital-based stoma nursing teams.

Review of the process

The proposed process, assessment form, local impact and cost-effectiveness will be reviewed by the local Stoma Team 6 months after acceptance onto the Joint Formulary and presented to the APC for review of the local classification.